EXHIBIT A

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Page 1
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                 UNITED STATES DISTRICT COURT
                FOR THE DISTRICT OF NEW JERSEY
 2
                       CAMDEN VICINAGE
                         MDL NO. 2875
 3
      IN RE: VALSARTAN, LOSARTAN,
 4
      AND IRBESARTAN PRODUCTS
      LIABILITY LITIGATION
 5
 6
      THIS DOCUMENT RELATES TO
 7
      Gaston Roberts et al. v.
      Zhejiang Huahai
      Pharmaceutical Co., et al.,
 8
 9
      Case No. 1:20-cv-00946-RMB-SAK:
10
                                      :
11
12
13
                 Videotaped remote deposition of
      NADIM MAHMUD, M.D., taken in the above-entitled
14
15
      matter before Suzanne J. Stotz, a Certified
16
      Court Reporter (License No. 30XI00184500) and
17
      Notary Public of the State of New Jersey,
      taken on Friday, May 2, 2025, commencing at
18
      9:03 a.m. EDT.
19
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2.1
22
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2.4
25
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PageID: 113949

Page 2		Page 4
1 APPEARANCES:	1 INDEX (Continued)	
2 3 (Via videoconference)	3 EXHIBITS (Continued)	
NIGH, GOLDENBERG, RASO & VAUGHN, PLLC	4 Fuhikit Description Bose No.	
4 BY: DANIEL A. NIGH, ESQ.	Exhibit Description Page No. 5	
BY: C. BRETT VAUGHN, ESQ.	Exhibit 9 Medical Record, Bates 243	
5 BY: KATHRYN AVILA, ESQ. BY: STEPHANIE IKEN, ESQ.	6 labeled Restricted Confidential	
6 14 Ridge Square NW, Third Floor	7 Information	
Washington, D.C. 20016	GRobertsJr-AMG-000051 8 through Restricted	
7 (202) 792-7927	Confidential	
dnigh@nighgoldenberg.com	9 Information	
8 bvaughn@nighgoldenberg.com avila@nighgoldenberg.com	GRobertsJr-AMG-000053	
9 siken@nighgoldenberg.com	Exhibit 10 Case report entitled, 256	
Attorneys for the Plaintiffs	11 "Adverse Effects of Proton Pump Inhibitors	
10	on Platelet Count: A	
11	Case Report and Review	
(Via videoconference) 12 KIRKLAND & ELLIS LLP	13 of the Literature," by Subhajit	
BY: NINA R. ROSE, P.C.	14 Mukherjee, et al.	
13 1301 Pennsylvania Avenue, N.W.	15 Exhibit 11 North Baldwin 280	
Washington, D.C. 20004	Pharmacy, pharmacy 16 record for Gaston J.	
14 (202) 389-3394	Roberts, Jr.	
nina.rose@kirkland.com	17 Evhibit 12 Study Entitled 281	
15 Attorneys for the Defendants16	Exhibit 12 Study Entitled, 281 18 "Hydrochlorothiazide-	
17	Induced	
18	19 Thrombocytopenic Purpura," by	
ALSO PRESENT:	20 Kingsley C.	
19	Okafor, et al.	
William David Geigert, Videographer 20	21 Exhibit 13 Medical Record, Bates 292	
21	22 labeled Restricted	
22	Confidential 23 Information	
23	23 Information GRobertsJr-AMG-000040	
24 25	24 25	
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3 EXAMINATION Page No.	3 EXHIBITS (Continued)	
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5 BY MR. VAUGHN 8	5 Einhihit 14 Madical records Potes 221	
6	Exhibit 14 Medical records, Bates 321 6 labeled Restricted	
7	Confidential	
8 EXHIBITS 9	7 Information	
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 10 Exhibit Description Page No. 11 Exhibit 1 Expert Report of Nadim 20 Mahmud, M.D., M.S., 	8 through Restricted	
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1	INDEV (Continued)	1	Page 8
2	INDEX (Continued)	1	request.)
3	EXHIBITS (Continued)	2	NADIM MAHMUD, M.D.,
4	211112112 (commune)	3	having first been duly sworn, was examined and
	Exhibit Description Page No.	4	testified as follows:
5		5	THE COURT REPORTER: Thank you.
	Exhibit 18 Author manuscript 404	6	You may proceed.
6	entitled, "Hepatocellular	7	EXAMINATION
7	Carcinoma Tumor Volume	8	BY MR. VAUGHN:
,	Doubling Time: A	9	Q. Hello, Doctor.
8	Systemic Review and	10	Am I saying your name right,
	Meta-analysis," by	11	Dr. Mahmud?
9	Piyush Nathan, et al.	12	A. Yes. You've got it, Counselor.
10		13	Q. Awesome have you ever been deposed
11 12		14	before?
13	(Exhibits attached to transcript.)	15	A. No. This is my first time.
14	(=	16	Q. Have you ever served as an expert
15		17	witness before?
16		18	A. No, I have not.
17		19	Q. Okay. I want to run through just
18 19		20	some of the basic rules. I'm sure Ms. Rose
20		21	went over them with you.
21		22	We'll do our best not to talk over
22		23	
23		١	each other. I'll ask you a question. Wait a
24		24	few seconds so Nina can launch an objection if
25		25	she wants before you respond. I will do my
1	Page 7 THE VIDEOGRAPHER: Good morning.	1	Page 9 best to let you fully respond before I ask my
2	We are now on the record. My name is Bill	2	next question. Sometimes with, you know, video
3	Geigert. I'm a videographer for Golkow, a	3	or if we get too conversational, we might talk
		Ι.	
4	Veritext Division. Today's date is May 2nd, 2025, and the time is 9:03 a.m.	4	over each other. So let's try not to do that.
5		5	If we do, the court reporter will let us know
6	This remote video deposition is	6	so we can stop so she can get a good record.
7	being held in the matter of Valsartan,	7	I'll try to not talk too fast so she can get a
8	Losartan, and Irbesartan Products		good record; I have a tendency to. So she'll
9	Liability Litigation. The deponent is	l	let us know if either of us are talking too
10	Dr. Nadim Mahmud.	10	fast.
11	All parties to this deposition are	11	If I ask any questions that you
12	appearing remotely and have agreed to the	12	don't understand, you can just ask me to ask it
13	witness being sworn in remotely.	13	again or to rephrase. Does that make sense?
14	Due to the nature of remote	14	A. Yes. That makes sense.
15	reporting, please pause briefly before	15	Q. And when you're answering questions
16	speaking to ensure all parties are heard	16	let's try and do a yes, no or something that's
17	completely.	17	not a head nod just so that she can transcribe
18	All counsel will be noted on the	18	it. Does that make sense?
19	stenographic record.	19	A. Yes, it does.
20	The court reporter is Suzanne	20	Q. And if you answer a question, we
21	Stotz, and she will now swear in the	21	are going to assume that you understood the
22	witness.	22	question. Does that make sense?
	THE COURT REPORTER: Could you	23	A. Yes, that's fair.
23			
23 24	raise your hand.	24	Q. And then I typically take breaks

Page 10 Page 12 1 depending on the meeting. There was different 1 coffee while I'm going. 2 If you ever need a break, though, 2 counsel that attended different meetings, so 3 just let me know. As long as we're not, like, 3 Ms. Rose was present, Mr. Trangle, Ms. Davidson 4 mid-document or, like, midline of, questioning, 4 I believe is her last name. Those are the we'll take a break or find the quickest break 5 three that I recall. that we can take. Okay? 6 And prior to being retained for 7 Sure. That sounds good. this litigation, were you familiar with the A. substance N-Nitrosodimethylamine, which is 8 Did you bring any notes with you Q. 9 today? 9 abbreviated NDMA? 10 A. Only my expert report and 10 Yes, I was familiar with generally 11 what nitrosamines are. We -- during the course 11 Dr. Siddiqui's expert report. 12 of medical education we learn a little bit Q. Do you have those printed off? 12 I have them on my computer, not 13 A. 13 about nitrosamines. I wasn't intimately 14 printed physically. 14 familiar with, you know, literature related to Q. Okay. So is there any typed notes 15 NDMA-contaminated Valsartan specifically in any 15 16 that go along with it or just the report? 16 detail. 17 A. Just the reports. 17 Q. Were you familiar with NDMA 18 Do you have any programs open on specifically prior to this litigation? 19 your computer other than Zoom and whatever 19 Yes. 20 you're using to view the reports? 20 And what was your understanding of Q. 21 A. I have my Outlook inbox open, but 21 NDMA prior to this litigation? 22 I'm happy to close that if necessary. 22 So NDMA, again, is mostly Q. Yeah. If you don't mind closing 23 familiarity from medical school. We learn 24 that and no messaging with anyone outside while about different nitrosamines, NDMA, other we're doing the depo. 25 nitrosamines as well, mostly in the context of Page 11 Page 13 1 dietary exposures from my recollection. It was 1 A. Yeah. Okay, that's closed. 2 Q. Is anyone else with you currently 2 many years ago. But that's I think when I was 3 in the room? 3 first introduced to what NDMA is. A. No. Just me. Q. And what does class do you think 4 5 And I don't want to know any 5 you would have been in that introduced you to 6 communications you've had with attorneys, any 6 NDMA? of the substance, but did you prepare with 7 A. I believe it would have been 8 attorneys prior to this deposition? biochemistry or biochemistry as applicable to 9 Yeah. I met with counsel to review medicine type of course. It's one of the first 10 aspects of what a deposition is and what to year courses we take in medical school. 10 11 expect and some logistics. 11 Q. And did you have any courses after 12 Q. How many times did you meet with 12 that first year of medical school --

aspects of what a deposition is and what to
expect and some logistics.

Q. How many times did you meet with
counsel?

A. Throughout the entire course of my
involvement in the case or just leading up to
the deposition?

Q. Leading up to the deposition?

A. Perhaps on three occasions.

Q. And approximately how many total
hours?

If I have to approximate, maybe on

And who all was present at those

My recollection -- so it varied

MS. ROSE: Object to the form. 13 14 BY MR. VAUGHN: 15 Q. -- in NDMA? 16 It's hard to recall specifically. I don't think -- my recollection is we learned about it in this kind of principles of biochemistry type of class. I couldn't say 20 concretely if we encountered NDMA again in our secondary classes. The program I went to at 22 Stanford we moved relatively quickly into 23 clinics, so there was a lot of clinical 24 exposure. So most of our didactic 25 electro-based content is in the first year.

4 (Pages 10 - 13)

A.

Q.

24 meetings?

22 the order of perhaps four hours.

21

23

25

Page 14 Page 16 1 Did you guys review studies of NDMA 1 drug development, things like this that 2 while you were in medical school? 2 requires a broad knowledge base of, you 3 A. It's likely that they showed us know, some degree of basic science 4 4 some animal literature. That class in literature as well. 5 5 particular is very basic science focused, So, yes, I mean obviously I'm not treating animals in my practice, but it's talking about, you know, molecular pathways, 6 enzymatic pathways, things of that nature. And 7 relevant to learn about broad principles so I think in that context, you know, I expect 8 of animal research that may or may not be 9 they showed us some basic science literature relevant to humans, depending on the 10 from animal studies. 10 particulars of the research question and 11 Q. And what was the purpose of 11 the study. 12 learning about NDMA in medical school? 12 BY MR. VAUGHN: MS. ROSE: Object to the form. 13 13 In school your teacher was 14 THE WITNESS: Yeah. I think, you presenting those to you as NDMA, the metabolic 15 know, broadly speaking, you know, they try pathways in animals, did they think that was to educate us about a wide range of relevant for how it might impact humans? 16 16 17 metabolic pathways, enzymatic pathways, 17 MS. ROSE: Object to the form. and ways in which different substances, THE WITNESS: I'm not certain. I 18 18 19 different exposures can interact with 19 don't recall, you know -- I don't recall 20 these metabolic pathways. Oftentimes 20 that professor positing anything specific 21 there is a heavy focus on enzymatic 21 about that. I think that professor I 22 mechanisms and specific proteins or 22 think actually was -- I don't think he was 23 enzymes that are relevant in different 23 a clinician. I believe he was Ph.D. basic 24 24 types of pathways. And so I think that scientist, from my recollection, so he's 25 that was likely introduced in that 25 very focused on the basic science aspects Page 15 Page 17 1 context. 1 of this, not so much that's really direct 2 BY MR. VAUGHN: 2 clinical translation. 3 BY MR. VAUGHN: 3 Q. And do you recall what metabolic pathways NDMA interacts with in a human or in Q. And do you recall how long this 4 4 5 animals? course was where they were talking about NDMA? A. So, again, I don't recall any 6 Was it a single day or was this like for the 7 specific human data that they might have shared 7 entire semester they were discussing NDMA? wit us. Again, this is now well more than a 8 It was certainly not the entire decade ago, so it's hard to recall specifics of semester. I think we covered a wide range of 10 what they may have shown us, but it, you know, 10 subjects related to biochemistry and biophysics 11 is likely related to carcinogenesis in animals. were relevant. So I don't know, it might have Q. Did they tell you in medical school 12 12 been maybe two lectures at most, but I suspect 13 NDMA was likely carcinogenic in humans? 13 it was probably just a single lecture and not A. I don't recall hearing that 14 14 even an entire lecture dedicated to this. It 15 specifically, no. 15 was probably discussed in the context of other Q. And you were in medical school to 16 exposures and other pathways as well, though, 17 treat humans, not in veterinarian school to again, I can't recall with any real detail 18 treat animals, right? 18 because it was -- this was back in like 2008, MS. ROSE: Object to the form. 19 19 2009, so it was a long time ago. 20 THE WITNESS: That's true that 20 Q. So most of what you have learned about NDMA was through this litigation? 21 obviously our primary focus in medical 21 22 school is ultimately to learn to treat A. I think much -- yeah. So I think 22 23 humans, but we are also educated broadly 23 in this litigation, certainly as applied to 24 24 NDMA-contaminated Valsartan, yeah, this is the about the scientific literature and where 25 our understanding of molecular mechanisms, 25 first time I looked in real detail carefully at

	Page 18		Page 20
1	a lot of the literature from animal studies and	1	(Whereupon, Exhibit 1, Expert
2	human studies. This doesn't really come up in	2	Report of Nadim Mahmud, M.D., M.S.,
	the course of my routine care as a hepatologist	3	M.P.H., M.S.C.E., was marked for
	really at all. I've never had to posit that	4	identification.)
5	NDMA could have been plausibly linked to any	5	BY MR. VAUGHN:
6	liver related outcome in my practice. So, yes,	6	Q. All right. And are you able to see
7	I would say that the deep dive into the	7	it also on my screen where I'm screen sharing?
8	literature with respect to the specific	8	A. Yes, I can.
9	question in this case was done in the context	9	Q. If we need it. Is it zoomed in
10	of this case.	10	properly or is it zoomed out really far?
11	THE COURT REPORTER: I'm sorry,	11	A. It's somewhat zoomed out. I can
12	Doctor, if you could slow down a little	12	see it. It's very small, but I can see it.
13	bit, I would appreciate it. Thank you.	13	Q. Give me one second. Just play
14	THE WITNESS: My apologies.	14	around with it before I get going too far. Is
15	BY MR. VAUGHN:	15	that better or worse?
16	Q. Approximately what year do you	16	A. It's a little better.
17	believe you were in medical school when you	17	Q. Okay. I guess first, do you have
18	were going over NDMA?	18	any corrections that you would like to make to
19	A. I think I stated it to be the year	19	your expert report before we get going?
20	2008 to 2009. That would have been my first	20	A. Yes. And thanks for offering the
21	year of medical school at Stanford.	21	opportunity. There is one correction I'd like
22	Q. And you submitted an expert report	22	to make that I just found yesterday when I was
23	in this litigation, correct?	23	just rereading my report.
24	A. I did, yes.	24	Let's see, it's on page let me
25	Q. We are going to drop	25	search this document. On page 21 at the very
	Page 19		Page 21
1	MS. ROSE: Mr. Vaughn, sorry, I am	1	bottom paragraph that begins with "Fifth." So
2	so sorry to interrupt, and I should stated	2	it says, "Fifth, the cross-sectional imaging
3	it right at the beginning of the	3	performed on Mr. Roberts in April 2016
4	deposition, but Dr. Mahmud had a	4	independently confirmed the presence of
5	typographically correction to something in	5	cirrhosis. On 4/19/2016, Ms. Roberts underwent
6	his report that he wanted to raise at the	6	a CT of the abdomen and pelvis. The treating
7	deposition.	7	radiologist's report states:" And then I have
8	MR. VAUGHN: I was just about to	8	a quote there. I erroneously so I initially
9	ask if he had any corrections.	l	intended to pull a quote from the radiology
10	MS. ROSE: Okay, well, perfect.	10	report that's referenced further up in my
11	MR. VAUGHN: You beat me to my next	11	expert report during the medical records
12	question, Nina.	12	reviewed portion. And I erroneously put that
13	MS. ROSE: I'm sorry, I had	13	quote around my own interpretation. That's why
14	forgotten to raise it at the very	14	it begins with "'My review of this imaging."'
15	beginning.	15	I am intending that to come from me. So "'My
16	THE WITNESS: I also did.	16	review of this imaging demonstrates a very
17	BY MR. VAUGHN:	17	clear nodular contour of the liver," that's
18	Q. Not not a problem. We're going	18	attributable to my own interpretation of the
19	to drop that first, the report into the share	19	imaging. The quote that I intended to pull
20	file. And let me know once you can access	20	there is found on page 8 where I quote the
21	that, and I will try and share screen it.	21	treating radiologist report of the CT scan.
22	A. All right. I think I'm able to see	22	And I am happy to read that into the record.
23	it as Exhibit 1.	23	So that report states, "Peripheral margin of
24	it do Lamuit 1.	24	the liver is somewhat lobulated, particularly
25		25	along the infra aspect of the left lobe."
			aiong the inita aspect of the left 100c.

1	Page 22	1	Page 24
$\frac{1}{2}$	"'Although nonspecific, findings above may be	1	own? It was just this one here with the quote?
2	evidence of liver cirrhosis.'" That is what I	2	A. Yes, that's right.
3	intended to pull down there. So my apologies	3	Q. Okay. I understand. Thank you for
4	for the oversight.	4	that clarification.
5	Q. So this part I'm highlighting is	5	A. Thank you.
6	what you're talking about?	6	Q. Are there any other corrections in
7	A. Yes. Specifically right after	7	your report?
8	the quote that's given right after the treating	8	A. No.
9	radiology radiologist's report states.	9	Q. Okay. And your purpose as an
10	Q. I'm sorry. Are you saying that	10	expert witness was to respond to the opinions
11	this quote should be different or that the	11	offered by Dr. Siddiqui; is that correct?
12	person that it is attributed to should be	12	A. Yes. My understanding is I'm
13	different?	13	offering an opinion as to specific causation
14	A. I don't intend to quote that at	14	expert to respond to the plaintiff medical
15	all, actually.	15	expert witness, Dr. Siddiqui.
16	Q. So you're going to strike this from	16	Q. And you understand she was a
17	your report?	17	specific causation expert as well, correct?
18	MS. ROSE: I don't believe that is	18	A. Yes, I do understand that.
19	what the witness is saying.	19	Q. And did you review Dr. Siddiqui's
20	THE WITNESS: I'm not saying to	20	report?
21	strike it from the report. I'm saying you	21	A. Yes, I did.
22	can attribute what is quoted to me as the	22	Q. And did you review her supporting
23	expert witness. I intended	23	citations in the materials considered as well?
24	BY MR. VAUGHN:	24	A. Yes, I did.
25	Q. Okay. So sorry. As opposed to	25	Q. And are you aware that we've
	Page 23		Page 25
1	Page 23 the treating radiologist's reports, it would be	1	Page 25 already had general causation phase of this
1 2		1 2	
	the treating radiologist's reports, it would be		already had general causation phase of this
2	the treating radiologist's reports, it would be your opinion is and then this quote?	2	already had general causation phase of this litigation?
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	Page 26		Page 28
1	causal link that's allege in the case.	1	considered?
$\frac{1}{2}$	BY MR. VAUGHN:	2	A. Yes.
3	Q. And that the Court has found they	3	Q. And then you note deposition
4	have a sufficient basis to make those opinions?	4	transcripts. So you reviewed these deposition
5	MS. ROSE: Object to the form. The	5	transcripts as well?
6	doctor is not here to comment on the	6	A. Yeah. The deposition transcripts
7	Court's rulings or what it means.	7	listed, yes, these ones I have reviewed.
8	THE WITNESS: I am the not privy to	8	Q. Okay. And then like some of these
9	the Court's rulings on that specific	9	you actually cite in your report, like
10	matter.	10	Dr. Hooks' deposition, correct?
11	BY MR. VAUGHN:	11	A. That's correct.
12	Q. Did you see that Dr. Siddiqui	12	Q. Did you review any of these in more
13	reviewed the plaintiff's general causation	13	detail than others?
14	report, such as Dr. Panigrahy, the cancer	14	A. I would say that some of them were
15	researcher?	15	more relevant to my opinions. And so there are
16	MS. ROSE: Object to the form.	16	certain sections of certain depositions that I
17	THE WITNESS: You have to show me	17	found to be more relevant; and those are
18	specifically. I don't recall off the top	18	usually represented by areas that I have cited
19	of my head. But if that is listed in her	19	to support my opinions in the case. And then
20	list of reviewed materials, then I would	20	some depositions were less relevant. So, for
21	take her word for it.	21	1
22	BY MR. VAUGHN:	22	history from a pulmonologist is a little bit
23	Q. Okay. But Dr. Panigrahy's report	23	less relevant to this specific causation case.
24	is like 200-some pages. Do you recall if you	24	So, yes, I mean there was variation
25	reviewed his actual report and the basis of his	25	and which depositions I found to be more or
	Page 27		Page 29
1	report?	1	less informative to forming my opinions about
2	report? MS. ROSE: Object to the form.	1 2	less informative to forming my opinions about the case.
2 3	report? MS. ROSE: Object to the form. THE WITNESS: Dr. Panigrahy's	3	less informative to forming my opinions about the case. Q. Was Dr. Hooks one that you found
2 3 4	report? MS. ROSE: Object to the form. THE WITNESS: Dr. Panigrahy's reports, you would have to probably show	3 4	less informative to forming my opinions about the case. Q. Was Dr. Hooks one that you found informative?
2 3 4 5	report? MS. ROSE: Object to the form. THE WITNESS: Dr. Panigrahy's reports, you would have to probably show me. I can't recall specifically if I	3 4 5	less informative to forming my opinions about the case. Q. Was Dr. Hooks one that you found informative? A. Yes. Dr. Hooks was one of the
2 3 4 5 6	report? MS. ROSE: Object to the form. THE WITNESS: Dr. Panigrahy's reports, you would have to probably show me. I can't recall specifically if I reviewed that one in detail or not.	3 4 5 6	less informative to forming my opinions about the case. Q. Was Dr. Hooks one that you found informative? A. Yes. Dr. Hooks was one of the treating radiologists. And I did find both,
2 3 4 5 6 7	report? MS. ROSE: Object to the form. THE WITNESS: Dr. Panigrahy's reports, you would have to probably show me. I can't recall specifically if I reviewed that one in detail or not. BY MR. VAUGHN:	3 4 5 6 7	less informative to forming my opinions about the case. Q. Was Dr. Hooks one that you found informative? A. Yes. Dr. Hooks was one of the treating radiologists. And I did find both, you know, his notes and the medical record and
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	Page 30		Page 32
1	medical records of the plaintiff, Mr. Roberts?	1	was already identifying other very
$\frac{1}{2}$	A. Yes, I did.	2	significant well-established risk factors
$\frac{2}{3}$	Q. The next exhibit is going to be the	3	that I was very concerned were very likely
l .	invoice you produced with the Notice of		to have been related directly to his
4	Deposition or in response to the Notice of	5	· · · · · · · · · · · · · · · · · · ·
5			hepatocellular carcinoma.
6	Deposition. Let me know once you have access to that.	6	Again, I was in the process of
7	A. I can see it.	7	forming an opinion about NDMA-contaminated
8		8	Valsartan. And I think at point I was
9	Q. One second. All right.	9	just beginning to engage shortly after
10	So this invoice was on April 2nd,	10	that really was literature to review. So
11	2025?	11	I don't I think I had solidified an
12	A. Yes.	12	opinion about NDMA-contaminated
13	(Whereupon, Exhibit 2, Invoice	13	Valsartan's relevance to his particular
14	Number INV-01, dated April 2, 2025, was	14	case at that point.
15	marked for identification.)	15	Like I said, at that stage I was
16	BY MR. VAUGHN:	16	mostly getting the chronology together.
17	Q. All right. I see you started	17	And then, with my clinical background,
18	drafting your expert report here on 3/8/2025.	18	obviously as I'm putting together
19	Do you recall what you initially started	19	chronology, I identified risk factors that
20	drafting in your expert report that first day?	20	I think are relevant to, for instance,
21	A. I expect I you know, I spent a	21	cirrhosis, obesity, diabetes, so I was
22	lot of time prior to that reviewing the medical	22	aware of those things in the chronology.
23	records. And so at that time I believe I was	23	And that wasn't forming my evolving
24	starting to really try to piece together the	24	opinion of the case.
25	medical records kind of chronologically and get	25	
	Page 31		Page 33
1	a sense of the timeline. That's where I recall	1	BY MR. VAUGHN:
2	starting.		
-	<u> </u>	2	Q. And so at the time you started
3	Q. And at that time did you form an	3	drafting your expert report on March 8, 2025
	Q. And at that time did you form an opinion in this case?		drafting your expert report on March 8, 2025 you had not yet done any literature review on
3	Q. And at that time did you form an opinion in this case?A. It's hard to recall exactly on that	3	drafting your expert report on March 8, 2025 you had not yet done any literature review on NDMA; is that correct?
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	D 24		D 06
1	Page 34	1	Page 36 position to make an informed opinion.
$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	general process. I want to understand the facts of the case and the chronology of	$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	BY MR. VAUGHN:
$\frac{2}{3}$	the case, the comorbidities, et cetera,	$\frac{2}{3}$	
4	first. And then I take that knowledge of	4	Q. And then Dr. Siddiqui submitted her report on 3/10/2025; does that sound right?
5	the case to help me interpret the	5	A. I don't recall the exact date, but
6	literature through the appropriate lens.	6	that sounds roughly correct.
7	BY MR. VAUGHN:	7	Q. Okay. And so from that point on it
8	Q. So you started drafting your expert	8	looks like you billed 47 hours. Does that look
9	report prior to evaluating that NDMA	9	approximately right or do you want to add it
10	literature, correct?	10	up?
11	MS. ROSE: Object to the form.	11	A. It looks approximately correct. I
12	This has been asked and answered.	12	will take your word for the math. We can just
13	THE WITNESS: So there are	13	add it up, but that sounds about right.
14	obviously my report is very long. The	14	Q. Okay. And for that 47 hours that
15	entire document is 70 pages. And there	15	included more review of records, the review of
16	are aspects of the report that are not	16	literature, the drafting of your expert report,
17	directly related to the specific medical	17	and communicating with counsel; is that
18	records. I mean there is also my CV, for	18	correct?
19	instance. There is my summary of my own	19	A. Yes.
20	background qualifications, that is another	20	Q. Okay. As you said, you had a
21	aspect that I think I was probably	21	70-page expert report. So part of that 47
22	drafting early on in addition to the	22	hours was drafting your 40 or your 70-page
23	medical records, kind of chronological	23	expert report, correct?
24	review. So those aspects of the report,	24	A. Yes.
25	you know, they don't require a detailed	25	Q. Approximately how many of those
	Page 35		Page 37
1	literature review at that phase. It is	1	hours do you think were spent drafting your
2	really when I am talking about my opinions	2	expert report, the 70-page expert report, how
3	and supporting that with evidence and	3	many of those 47 hours?
4	literature, that is when the literature	4	A. I would be approximating, but
5	review becomes most relevant.	5	probably at least 20 of them.
6	BY MR. VAUGHN:	6	Q. Approximately how many of those
7	Q. Ad so are you saying that you draft	7	hours do you believe were communicating with
8	your report and then you find literature to	8	counsel?
9	support your opinions; is that correct?	9	A. Well, so those would be separate.
10	MS. ROSE: Object to the form. It	10	Of the 47 hours, I don't think there was very
11	misstates what the witness said.	11	much communication with counsel during this
12	THE WITNESS: No, that is not	12	phase. I have only listed it on one day, on
13	correct. I as a clinician and a	13	the 14th. You know, I had a meeting with
1 4 4		14	counsel, it was probably no more than two hours
14	clinician scientist, hopefully you have	1.7	T 1 d
15	seen my background, I'm a clinician	15	I would expect.
15 16	seen my background, I'm a clinician scientist, I have a high standard when I	16	Q. Two hours. And out of those 47
15 16 17	seen my background, I'm a clinician scientist, I have a high standard when I review medical records and studies. I	16 17	Q. Two hours. And out of those 47 hours, how many of those hours do you think
15 16 17 18	seen my background, I'm a clinician scientist, I have a high standard when I review medical records and studies. I maintain an open mind and I evaluate what	16 17 18	Q. Two hours. And out of those 47 hours, how many of those hours do you think were reviewing medical records?
15 16 17 18 19	seen my background, I'm a clinician scientist, I have a high standard when I review medical records and studies. I maintain an open mind and I evaluate what I view to be strengths and weaknesses of	16 17 18 19	Q. Two hours. And out of those 47 hours, how many of those hours do you think were reviewing medical records? A. So, let's see, I've given you 20
15 16 17 18 19 20	seen my background, I'm a clinician scientist, I have a high standard when I review medical records and studies. I maintain an open mind and I evaluate what I view to be strengths and weaknesses of the scientific literature, interpret that	16 17 18 19 20	Q. Two hours. And out of those 47 hours, how many of those hours do you think were reviewing medical records? A. So, let's see, I've given you 20 plus two so far, so that leaves 25 hours to
15 16 17 18 19 20 21	seen my background, I'm a clinician scientist, I have a high standard when I review medical records and studies. I maintain an open mind and I evaluate what I view to be strengths and weaknesses of the scientific literature, interpret that in the context of a specific case.	16 17 18 19 20 21	Q. Two hours. And out of those 47 hours, how many of those hours do you think were reviewing medical records? A. So, let's see, I've given you 20 plus two so far, so that leaves 25 hours to account for. Yeah, so I would say the records
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15 16 17 18 19 20 21 22 23	seen my background, I'm a clinician scientist, I have a high standard when I review medical records and studies. I maintain an open mind and I evaluate what I view to be strengths and weaknesses of the scientific literature, interpret that in the context of a specific case. So I went into this review with a very open mind to try evaluate the weight	16 17 18 19 20 21 22 23	Q. Two hours. And out of those 47 hours, how many of those hours do you think were reviewing medical records? A. So, let's see, I've given you 20 plus two so far, so that leaves 25 hours to account for. Yeah, so I would say the records review and literature review, a lot of that is happening in tandem as well as kind of
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1	Page 38		Page 40
1	specifically. It is not like I sat for 20	1	managing these patients and thinking about
1	hours and only drafted the report. I	2	these patients.
3	oftentimes was drafting while I am also	3	So I would say it was quite broad
4	reviewing records and literature. But I would	4	in terms of literature search. There were
5	say that, you know, probably an additional five	5	searches that were really focused on NDMA.
6	to ten of those hours are really looking at	6	There were searches that were really
7	dedicated sections of the records to double	7	focused on literature. And I did my best
8	check or triple check things or identify	8	to be comprehensive.
9	additional important points.	9	BY MR. VAUGHN:
10	Q. So five to ten hours on the medical	10	Q. Are you aware of what cumulative
11	records during that time probably?	11	dose of NDMA Mr. Roberts was exposed to?
12	A. Yes. Again, with the caveat that	12	A. Yes. I can't remember the exact
13	I'm often when I'm the hours I have given	13	number off the top of my head, but, you know, I
14	you when I'm, quote, unquote, "drafting the	14	would be happy to reference it with you.
15	report," I'm likely also looking back at	15	I know in I recall in
16	records as well as some literature. So a lot	16	Dr. Sawyer's deposition he outlines it, you
17	of these overlapping. I can't put them in	17	know, informed with the different expected
18	boxes so cleanly.	18	ranges of contamination per Valsartan tablet,
19	Q. And then would you have an estimate	19	which my recollection on the high end of the
20	of those 47 hours how many were spent on	20	estimate was around 20,000 micrograms
21	reviewing literature?	21	potentially per tablet. And then, you know, if
22	A. I suppose the remainder of the	22	you assume with perfect adherence where he took
23	math. So it's 25 minus 5 to 7, so, I don't	23	that dose every single day for the exposure
24	know, probably 18 to 20-ish hours.	24	period, you know, he arrives at the cumulative
25	Q. And would you consider most of that	25	dose. But I can't remember the exact number
	Page 39		Page 41
1	literature review was on the various causes of	1	off the top of my head. But I would be happy
2	liver cancer or was most of it on researching	2	to review that specific number again with you.
3	NDMA?	3	But that is the methodology that was used to
4	MS. ROSE: Object to the form.	4	calculate the cumulative dose.
5	TOTAL TAXABLE CO. T. C. 1.1		
1	THE WITNESS: I was fairly	5	Q. Does that number appear anywhere in
6	comprehensive in my approach. I tried to	6	Q. Does that number appear anywhere in your expert report?
6 7	comprehensive in my approach. I tried to identify really as much relevant	6 7	Q. Does that number appear anywhere in your expert report?A. I don't recall putting that number
6 7 8	comprehensive in my approach. I tried to identify really as much relevant literature to this case as possible.	6 7 8	Q. Does that number appear anywhere in your expert report?A. I don't recall putting that number in directly into the report.
6 7 8 9	comprehensive in my approach. I tried to identify really as much relevant literature to this case as possible. So I did searches both for NDMA in	6 7 8 9	 Q. Does that number appear anywhere in your expert report? A. I don't recall putting that number in directly into the report. Q. Did you consider that number in
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1	Page 42 case and be responsive to Dr. Siddiqui's expert	1	Page 44 BY MR. VAUGHN:
1		_	
2	report. You know, we don't routinely calculate	2	Q. And, therefore, you don't believe
3	cumulative dose exposures in this fashion for	3	there is any plausible capability of NDMA
4	most patients, except in perhaps very unusual	4	causing liver cancer in humans?
5	cases. So I looked at it through that lens in	5	MS. ROSE: Object to the form.
6	my capacity as a clinician and a clinician	6	THE WITNESS: I have not seen any
7	scientist; not a toxicologist.	7	high quality scientific evidence
8	Q. So you are not a toxicologist,	8	specifically in humans that
9	correct?	9	NDMA-contaminated Valsartan can cause
10	A. Correct, I am not a toxicologist.	10	hepatocellular carcinoma specifically in
11	Q. And you are not giving any	11	humans. So I reserve the right to revise
12	toxicology opinions in this case, correct?	12	that opinion if there is a new study that
13	A. No, I am not offering any opinions	13	comes out that's very well conducted that
14	as a toxicologist because I am not one. I may	14	accounts for potential biases and
15	have some opinions that may be in some way	15	confounders and limitations to demonstrate
16	related to toxicology, again, with my	16	from a causal inference standpoint that it
17	perspective as a clinician primarily.	17	is causally linked to HCC, yeah, I would
18	Q. Have you investigated what dose of	18	reserve my right to revise the opinion if
19	NDMA it would take to give a human liver	19	a new study comes out.
20	cancer?	20	But based on the literature I found
21			
	MS. ROSE: Object to the form.	21	and reviewed, including that which has
22	THE WITNESS: So my review of the	22	been cited by Dr. Siddiqui, I don't find
23	human literature is that it's very much	23	any compelling well-established evidence
24	not at all well-established that NDMA is	24	to show that at the doses that have been
25	even plausibly capable of causing	25	studied that there is any well-established
1	Page 43	1	Page 45
1	hepatocellular carcinoma specifically in	1	link with hepatocellular carcinoma in
2	humans. A lot of this is imputed from the	2	humans.
3	animal literature. And so I do have a	3	BY MR. VAUGHN:
4	sense from the animal literature of what	4	Q. Did you look at any higher doses?
5	doses of NDMA were given and observed to	5	So outside of Valsartan, just NDMA in general,
6	be linked with different types of cancers,	6	do you have any opinions on what dose it would
7	including liver cancers. And very briefly	7	take to cause liver damage?
8	they're extremely high doses that are used	8	MS. ROSE: Object to the form.
9	in general in animal studies, usually on	9	THE WITNESS: Yes. As I said, most
10	the scale of milligrams per kilogram per	10	of the the highest quality evidence for
11	day, which are orders of magnitude higher	11	NDMA in carcinogenesis really comes from
12	than what is studied or observed in these	12	well controlled experimental settings in
13	epidemiologic studies in humans.	13	animals where the doses that are being
14	So to that extent, there is no real	14	used are at a completely different order
15	human data that very clearly	15	of magnitude than routine dietary
16	scientifically in a way it's	16	exposures that humans have or even
17	well-established links NDMA in humans	17	environmental exposures or certainly
18	specifically to hepatocellular carcinoma.	18	pharmaceutical level exposures, there are
19	So it's hard to make a statement about	19	orders of magnitude different. So I am
			_
20	what dose could potentially do that.	20	not comfortable as a clinician and a
21	But if you try to impute from the	21	clinician science translating directly
22	animal literature, animals require	22	from an animal study, you know, in a very
23	extremely high doses relative to what's	23	different setting in a totally different
24	been studied in humans to observe those	24 25	model, you know, rodents versus humans, for instance, you really cannot take a
25	effects.		

	D 46		D 40
1	Page 46 one-to-one translation from an animal	1	Page 48 something to someone who weighs 250
2	study to a human study. So I rely on the	2	pounds, there is a different expected
$\frac{2}{3}$	human studies to make those ascertainments	3	effect than if you gave the same absolute
		l	• •
4	of what is expected to be observed in	4	dose to someone who weighs 120 pounds.
5	humans.	5	So those principles I understand as
6	The summary I have given you is	6	a clinician in terms of dosing, you know,
7	basically that I don't find any compelling	7	milligrams or whatever per weight. Those
8	evidence to really demonstrate that link	8	principles are important and I think are
9	in humans.	9	translatable to some extent between animal
10	BY MR. VAUGHN:	10	and human studies.
11	Q. And because you are a clinician,	11	BY MR. VAUGHN:
12	not a toxicologist, you don't do that dose	12	Q. In your opinion is NDMA a mutagen?
13	conversion from animals to humans, correct?	13	A. In my opinion in animal studies
14	MS. ROSE: Object to the form.	14	NDMA has been plausibly linked to being
15	THE WITNESS: Like I said, I am not	15	mutagenic, yes, for DNA in animals.
16	a toxicologist. But as a clinician, I do	16	Q. What do you mean by plausibly
17	understand principles of dosing	17	linked?
18	medications. So I do prescribe	18	A. I find the evidence from animal
19	medications and, you know, I do dose	19	studies to be scientifically sound. And,
20	medications appropriately for humans. So	20	again, I am not a basic scientist myself; but,
21	I understand principles of doses in	21	you know, they have explored some of the
22	concentrations. So that's something that	22	potential mechanisms in the basic science
23	I think any clinician should understand.	23	literature to understand how it could plausibly
24	So there is certain aspects of	24	lead to DNA damage in mutations. For instance,
25	toxicology that obviously I am not an	25	there is literature that demonstrates that NDMA
	Page 47		Page 49
1	expert on and wouldn't claim to be an	1	in the basic science setting can act as an
2	expert on, but I do understand	2	alkylating agent for DNA which can lead to DNA
3	concentrations.	3	mutations. So I accept that in the basic
4	And so milligrams per kilogram,	4	science animal literature NDMA does have this
5	which is a very commonly used way of	5	very plausible mechanistic explanation for how
6	thinking about a concentration of	6	it could lead to DNA damage.
7	something, you can look at what those	7	Q. Can those DNA damage and mutations
8	doses are in animals and compare them to	8	then lead to cancer in those animals?
9	humans. And that is relevant, because	9	A. Yeah, I do think that that's
10	obviously, you know, animals, like	10	plausible. And, you know, the scenario of
11	rodents, are obviously very different in	11	that I think in Dr. Sawyer's deposition I'm
12	size to humans, so it is relevant to know	12	sorry, his expert report, from my recollection,
13	how many milligrams or nanograms or	13	he does go over some of the mechanisms of how
14	micrograms per kilogram are given to an	14	NDMA in the animal basic science setting could
15	animal. It is actually an additional	15	act as an initiator and as a promoter in the
16	limitation of the human studies that there	16	carcinogenesis pathway. And I think that there
17	is no accounting for weight in human	17	is likely sufficient evidence in the animal
18	patients.	18	literature to show that in that particular
19	So like if you just as a brief	19	setting NDMA could you know, does have a
20	example, if you look at the FDA's	20	mechanistic basis for leading to cancer in
21	threshold limit of 96 nanograms per day of	21	animals in those basic science animal studies.
22	NDMA, they don't account for kilograms,	22	Q. Do you believe that NDMA does not
23	they don't account for body weight of	23	cause DNA mutations in humans?
24	individuals; but any clinician ought to	24	MS. ROSE: Object to the form.
25	know that if you give a certain dose of	25	THE WITNESS: So, again, my
1 43	know that if you give a certain dose of	23	ine wiiness. 30, agam, my

1			
1	Page 50 opinions on that in humans are informed by	1	Page 52 on who they are. But, yeah, I suspect that if
2	the literature. And it's not as simple of	2	a drank ten liters of water today I might get
3	a question of binary does DNA cause this,	3	very sick and need to be hospitalized.
4	yes or no. You have to consider things	4	Q. In your research you did for this
5	like doses. Many things can potentially	5	case, did you come across the case studies of
6	have a toxic effect if you give a	6	humans dying from NDMA ingestion?
7	sufficiently high dose; but at much lower	7	MS. ROSE: Object to the form.
8	doses or routinely environmentally exposed	8	THE WITNESS: I did come across
9	doses it may not have that toxic effect.	9	case studies where, you know, an
10	So there is more nuance.	10	individual in a case report, for instance,
11	I mean even something as simple as	11	was allegedly exposed to NDMA and then
12	water, if you were to ask me if water can	12	later, you know, they died and there was
13	be toxic, if you drink enough of it, yes,	13	an autopsy done. And, for instance, I
14	it can be toxic, it can kill you.	14	recall one specific case report where on
15	So it's you have to, in my view,	15	the autopsy the patient had cirrhosis and
16	really think about the details, not just	16	it had some plausible NDMA exposure. So,
17	the binary yes or no does this cause this.	17	yes, I do recall coming case studies of
18	It's the details of the exposure, the dose	18	that nature, if that's what you're
19	of the exposure, the duration of the	19	referring to.
20	exposure, the latency, the biological	20	BY MR. VAUGHN:
21	plausibility of the mechanisms, you have	21	Q. What do you mean by plausible NDMA
22	to consider all of these things together	22	exposure? Do you remember how they were
23	when you are making an assessment of	23	exposed?
24	whether a particular exposure like NDMA or	24	A. You would have to show me which
25	a particular patient, based on their	25	specific case report you are thinking of.
		23	· · · · · · · · · · · · · · · · · · ·
1	Page 51 context, could have plausibly led to a	1	Page 53 The one that I'm trying to recall
2	cancer like hepatocellular carcinoma.	2	is there may have been an occupational exposure
3	THE COURT REPORTER: I'm sorry,	$\frac{2}{3}$	to some nitrosamine. I don't remember the
4	Doctor, if I could remind you to slow down	4	specific context, but I think there was a case
5	a little bit.	5	report I remember seeing that there is some
6	THE WITNESS: I apologize.	5	report i remember seeing that there is some
7	THE WITHLESS. I apologize.	6	environmental exposure where the individual was
/		6	environmental exposure where the individual was
Q	BY MR. VAUGHN:	7	exposed to NDMA and likely other exposures as
8	BY MR. VAUGHN: Q. How much water does a human have to		exposed to NDMA and likely other exposures as well in sort of an industrial kind of setting.
9	BY MR. VAUGHN: Q. How much water does a human have to consume to kill them?	7 8 9	exposed to NDMA and likely other exposures as well in sort of an industrial kind of setting. So that's why I say plausible, because it is
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			5 5
1	Page 54 said, I rely on the scientific literature	1	Page 56 can conclude that it causes cancer in humans?
2	to inform my opinions about the potential	2	MS. ROSE: Object to the form. It
3	of something like NDMA to potentially, you	3	misstates the witness.
4	know, in a scientific valid way, cause an	4	THE WITNESS: No, I did not say
5	adverse outcome in a human.	5	that. I do not think that so I don't
		l	
6	And, generally speaking, case	6 7	think it would be ethical necessarily
7	series and case reports are not a valid		to it would not be ethical to perform a randomized control trial where you give
8 9	way scientifically to establish risk	8	individuals NDMA and randomize them to
10	factors. By definition those are	l	
	descriptives broadly speaking, like in	10	exposed or unexposed. But you can perform
11	terms of types of studies there are, there	11	very high quality observational studies
12	are descriptive studies, there are	12	using methodology that's very well thought
13	analytic studies. Descriptive studies do	13	out that can support causal inference.
14	not attempt to draw an association	14	I know this from my background as a
15	statistically between any exposure and an	15	clinician scientist. I'm a clinical
16	outcome; they just report what happens.	16	epidemiologist and so those are the types
17	And why that's so relevant is	17	of studies that I perform. I perform
18	for instance, you can't estimate a	18	observational epidemiologic studies,
19	relative risk from a case series or a case	19	including, from epidemiologic studies,
20	report. You need to perform an analytical	20	which can provide very strong evidence if
21	study. So some observational study or	21	they are well conducted and they account
22	interventional study like a randomized	22	for important biases.
23	trial.	23	So, no, I don't think the standard
24	I really I'm speaking fast so I'll	24	of evidence would require a randomized
25	slow down again.	25	trial. I don't think we would ever have a
	Page 55		Page 57
1	But that's very important because	1	randomized trial to demonstrate toxicity
2	we have a kind of a pyramid of quality of	2	of NDMA in humans. That would not be
3	evidence; and case series and case reports	3	ethical based on the animal literature.
4	are at the very bottom of the totem pole.	4	If you see a signal in the animal
5	No scientist will really rely on that to	5	literature that something may have the
6	adjudicate a risk factor.	6	potential to be carcinogenic in humans, we
7	So if somebody in a case report was	7	wouldn't be able to ethically randomize
8	given a high dose of NDMA and then died, I	8	patients to NDMA or not. And that's true
9	don't know for a fact that that individual	9	of many, you know, potential exposures
10	died because of the NDMA. They may have	10	that, you know, might have a potential
11	had other comorbid conditions or something	11	harm in humans whether or not they
12	else that resulted in them dying and it is	12	actually do. So that is an ethical
13	just a correlation. So that's why you	13	principle that's commonly applied in
14	need analytic studies to study individuals	14	randomized controlled trials.
15	who have an exposure and compare them to	15	BY MR. VAUGHN:
16	individuals who don't have the exposure	16	Q. So it would be unethical to give
17	and then account for different types of	17	humans NDMA at the dose that Mr. Roberts was
18	the confounders to minimize bias to make a	18	taking, correct?
19	very specific association between a	19	MS. ROSE: Object to the form.
20	potential exposure and an outcome. That's	20	THE WITNESS: So I think, if I just
21	where I kind of rank those case series and	21	kind of read the question properly, if
22	case reports when I review literature.	22	this was a randomized trial so Mr.
23	BY MR. VAUGHN:	23	Roberts' exposure was quite different;
24	Q. And so you're saying you would need	24	it's from a contaminated pharmaceutical.
25	a randomized trial on NDMA in humans before we	25	Like a randomized trial would be done in
25			

1	Page 58	1	Page 60
1	an interventional setting where someone is	1	are careful to do this, but, like I said, I
2	given just NDMA as an exposure versus a	2	understand the general principles of what they
3	placebo. But, in general, probably at,	3	do. They look at the animal literature and see
4	you know, any dose above the FDA threshold	4	what dose the animals may potentially be
5	it would be unethical to randomize someone	5	harmful in humans and then they add a huge
6	to that daily exposure versus not. BY MR. VAUGHN:	6	layer of margin of safety, because 1 additional
7		7	a cancer per 100,000 in my view is very, very
8	Q. And what is the FDA's reasonably safe threshold?	8	conservative. When you compare it to the
9 10		9	magnitude of risk factors in Mr. Roberts' case
11	MS. ROSE: Object to the form.	10	where, you know, there is like a 2 percent 2
12	THE WITNESS: My recollection of	11	to 4 percent annual instance of hepatocellular
13	their threshold is 96 nanograms per day. But there is a lot of context around that,	12	carcinoma in patients with cirrhosis, they are in completely different universes of risk. So
14	that the FDA provides in their own	13 14	that's just to give you an illustration of how
15	industry guidance.	15	conservative the FDA is.
16	It's so the FDA guidance very	16	But, to your question, I didn't
17	importantly is 96 nanograms per day over a	17	independently verify what animal study they
18	70-year human lifespan. And they arrive	18	chose to use to do the math to translate that
19	at that threshold imputing a very wide	19	to this very conservative risk scale for
20	margin of safety from the animal	20	humans, but I have no reason to doubt that they
21	literature to be very conservative, which	21	would do that with good scrutiny and rigor.
22	is I understand to be a typical FDA	22	Q. You said the 96 nanograms that the
23	practice. They want to offer a very	23	FDA set, did you do the math to see how many
24	conservative wide margin of safety. But	24	nanograms that would be over a lifetime? You
25	they translate from the animal studies to	25	talked about this is over 70 years. Do you
	Page 59		Page 61
1	a 70-year lifespan of a human. And they	1	know what cumulative lifetime dose would be of
2	arrive at the 96 nanograms per day of	2	96 nanograms?
3	daily exposure for 70 years. That would	3	A. I did do the math, actually, when I
4	translate to 1 additional cancer per	4	was thinking about this. I can't recall the
5	100,000 individuals with that exposure.	5	number off the top of my head, but I did do the
6	I provide that context here because	6	calculation. It's in the millions of nanograms
7	I think it's directly relevant to Mr.	7	of lifetime exposure over 70 years. Yes, I did
8	Roberts' case, because obviously he didn't	8	do that.
9	have a lifetime of exposure, he had less	9	Q. Which is a high exposure, right,
10	than two years of exposure to NDMA. So it	10	millions of nanograms?
11	doesn't really match the FDA's assumptions	11	MS. ROSE: Object to the form.
12	that go into, you know, toxic exposures,	12	THE WITNESS: I mean it's a large
13	which they understand to be have a very	13	number. I mean whether or not you
14	long latency period, which is why they	14	consider it to be a high exposure, it is
15	scale this over an entire human lifespan	15	still small relative to doses that were
16	of 70 years.	16	used in animal studies. It is still
17	But that's my understanding of the	17	orders of magnitudes smaller than what is
18	FDA threshold to answer your question.	18	used in the animal literature, but yes.
19	BY MR. VAUGHN:	19	So nanograms, obviously there are orders
20	Q. Do you agree with the FDA's	20	of magnitudes smaller than the milligrams.
21	calculation?	21	And, like I said, the animal studies, they
22	A. So, you know, as a clinician, I'm	22	are typically dosing animals on the order,
23	not a drug regulator, I don't work for the FDA,	23	you know, in the milligrams scale of
24	I don't, you know, independently verify their calculations. I assume that folks in the FDA	24	concentration. So nanograms is ten to the
25	carculations I assume that tolks in the HILL	25	negative ninth. Milligrams is ten to the

	Page 62		Page 64
1	negative third. So they are orders of	1	conservative scenario where I will just
2	magnitude different, but that's the math.	2	to take to argue the side that he got
3	I mean that's the math the FDA arrives at	3	the maximal exposure for the hypothetical,
4	it is in the range of millions of	4	if he did, in fact, get a high dose every
5	nanograms over a lifetime.	5	single day for as long as he was
6	BY MR. VAUGHN:	6	prescribed Valsartan, he would have had,
7	Q. And do you recall Mr. Roberts'	7	from my calculations, probably a five- to
8	cumulative exposure to NDMA?	8	six-fold higher exposure than the lifetime
9	MS. ROSE: Object to the form.	9	exposure limit from the FDA.
10	THE WITNESS: I do recall his	10	And the reason why I gave all the
11	exposure. Like I said before, I think he	11	context of how he arrives at that is what
12	is the high end. So if we take the most	12	that would mean for him is he would have
13	conservative estimate and assume that he	13	had over a lifetime, if there were 100,000
14	had the maximal possible exposure, which,	14	people just like Mr. Roberts who had that
15		15	
16	again, is very conservative from the plaintiff's perspective, that would give	16	exposure spread out over a lifetime, 5 to 6 of them out of that 100,000 might have
17	him 20,000 micrograms I'm sorry, 20,000	17	developed a liver cancer if we accept
18	•	18	
19	nanograms per day. 20,000 nanograms per day of exposure.	19	hypothetically that there is a well-established link. And, again, my
20	And when I was thinking about the	20	position is that there is not a
21	FDA's cumulative lifetime exposure, I did	21	well-established link demonstrated, but
22	calculate Mr. Roberts' Cumulative exposure	22	that is me being as charitable as possible
23	over his shorter window of time, because	23	to the plaintiff position is at most he
23		24	would have had, you know, 5 to 6 out of
25	obviously he was getting a daily exposure above the FDA's threshold limit. And his	25	· · · · · · · · · · · · · · · · · · ·
23		23	100,000 risk of developing an HCC.
1	Page 63 lifetime exposure was higher than the	1	Page 65 That's setting aside all the issues
2	FDA's threshold lifetime limit. And when	2	of temporality and latency, which I think
3	I did the math and, again, I would have	3	are bigger problems honestly. It's
4	to we could independently do the	4	completely implausible to develop a
5	calculations again if necessary, but off	5	hepatocellular carcinoma over the time
6	the top of my head my recollection was he	6	course that Mr. Roberts was exposed.
7	was exposed over his window of time to	7	But on the dosing question
8	somewhere in the ballpark of 5 to 6 times	8	specifically, that's what I would say.
9	above the lifetime threshold of the FDA's	9	BY MR. VAUGHN:
10	limit. That's my recollection.	10	Q. And so you think because he had 5
11	Q. And so the FDA's lifetime limit,	11	to 6 times the dose of what the FDA says is a
12	Mr. Roberts was exposed to several times higher	12	lifetime dose and he had that dose in a
13	than that in just a two-year period?	13	two-year period, you think it is just a 5 times
14	A. Yes.	14	higher risk of 5 out of 100,000 or 6 out of
15	MS. ROSE: Object to the form.	15	100,000; is that your opinion?
16	THE WITNESS: I'm sorry.	16	MS. ROSE: Object to the form.
17	Yes. Again, assume, taking the	17	THE WITNESS: So just to clarify,
18	assumptions, all the conservative	18	you know, I would be translating that I
19	assumptions, which are likely not to be	19	mean for a one-to-one comparison to the
20	true, it is unlikely that he truly was	20	FDA's lifetime limit you have to assume a
21	getting the maximal NDMA exposure with	21	lifetime of chronic exposure for Mr.
22	every single pill and it is unlikely that	22	Roberts as well, which, as you said, he
23	he was we don't even know if he was	23	did not have. He had a much more
24	adherent to taking a pill every day. But	24	concentrated shorter window exposure.
25	if I am taking, again, the most	25	So I'm just giving you the numbers
43	n i am taking, agam, the most	23	50 m just giving you the numbers

	Page 66		Page 68
1	if he had had that exposure spread out	1	hepatocellular carcinoma.
2	over 70 years you would expect that his	2	So it is really one of many points,
3	risk of developing a cancer, if we were to	3	but I'm putting emphasis on it now because
4	accept that there is a true causal link,	4	that is the area that we are talking
5	which, again, I don't accept for humans,	5	about.
6	would be 5 to 6 out of 100,000.	6	BY MR. VAUGHN:
7	I think it's my position is that	7	Q. In the human do you think the
8	when you additionally account for the fact	8	human body is able to repair the DNA damage
9	that he had a very short concentrated	9	that NDMA causes?
10	exposure, it's even less plausible for him	10	MS. ROSE: Object to the form.
11	to have developed a hepatocellular	11	THE WITNESS: So, again, I don't
12		12	_
1	carcinoma, because toxic exposures causing		accept that there is I don't accept
13	solid tumors there is typically a very	13	that there is really well-founded
14	long latency. It's usually many, many,	14	literature to demonstrate carcinogenicity
15	many years or decades before somebody	15	of NDMA specifically in humans. But with
16	would develop a solid tumor from any toxic	16	that caveat, if I were to hypothetically
17	exposure. That I think is actually an	17	assume that NDMA could do that, the
18	extremely important point in this case,	18	punitive mechanism in animals is that
19	that he started NDMA and then over a	19	it's that toxic metabolites from NDMA
20	relatively short period of time was then	20	can lead to DNA damage through things like
21	formally diagnosed with hepatocellular	21	alkylation of the DNA and things like
22	carcinoma.	22	that.
23	The carcinogenesis sequence that I	23	Cells are equipped with mechanisms
24	alluded to previously, induction,	24	to repair DNA. There are DNA repair
25	promotion, aggression, that Dr. Sawyer	25	mechanisms, yes. So cells can do this.
	Page 67		Page 69
1	also mentions and he really doesn't	1	That's why it's not a guarantee that a
2	talk about latency of those periods,	2	cell that has DNA damage, it's not a
3	unfortunately there is a very long	3	guarantee that that cell will eventually
4	latency between these steps. It takes a	4	turn into a cancer. We have many
5	long time for a healthy cell to acquire	5	safeguards in our cells and DNA repair
6	mutations that then lead to	6	mechanisms to prevent that from happening.
7	carcinogenesis; it's typically decades.	7	It's really only when someone is exposed
8	So that's I think an additional	8	to very chronically to a carcinogen that
9	problematic element to try to make a	9	provides the right environmental milieu
10	causal association in this specific case.	10	around those types of cells that have
11	BY MR. VAUGHN:	11	acquired DNA damage that they will acquire
12	Q. Is your opinion based more on the	12	more DNA damage and mutations over time
13	latency than the carcinogenicity of NDMA?	13	that serve as precursors to potential
14	MS. ROSE: Object to the form.	14	cancer down the line.
15	THE WITNESS: No. So when I make	15	And that is an articulation it's
16	my opinion I try to weigh all the relevant	16	important to articulate that demonstrates
17	factors. I'm highlighting you know,	17	why it's such a slow process. I can't
18	because you're asking about the dosing of	18	think of any specific toxic exposure that
19	the Valsartan, I'm highlighting aspects of	19	could plausibly cause hepatocellular
20	my opinion that are relevant when thinking	20	carcinoma over such a short window. Even
21	about that particular question. But there	21	the most toxic exposures that I am aware
22	are other elements of my opinion that are	22	of in my practice as a hepatologist, like
23	equally, if not more, relevant to my	23	aflatoxin or extremely high-dose
24	opinion that NDMA-contaminated Valsartan	24	
1	=		radiation, the latency period between
25	was really not relevant to Mr. Roberts'	25	initial injury and chronic exposure and

1			
1	Page 70	1	Page 72
1	hepatocellular carcinoma on the shortest	1	3
2	time scale is probably five to ten years.	2	But you know, but dietary
3	So, yes, I mean, we are equipped	3	studies are oftentimes fraught with lots of
4	with mechanisms in our cells to repair	4	
5	this damage. And it requires very, very	Ι.	independently to be, you know, strong
6	chronic long-term exposure to you know,	6	
7	repeated chronic exposure to a carcinogen	7	NDMA and liver cancer or, you know, liver
8	to cause these changes that result in a	8	cirrhosis, no.
9	cancer.	9	MR. VAUGHN: Okay. Now's a good
10	MS. ROSE: Mr. Vaughn, we've been	10	time for a break, Nina.
11	going for about an hour. Are you at a	11	MS. ROSE: Great.
12	good place for a break?	12	THE VIDEOGRAPHER: Off the record
13	If you are in the middle of	13	at 10:10 a.m.
14	something, we can certainly keep going for	14	(Whereupon, a break was taken.)
15	a little bit; but I wanted to raise that.	15	THE VIDEOGRAPHER: We are back on
16	MR. VAUGHN: You're good. Let me	16	the record at 10:24 a.m.
17	ask one question.	17	BY MR. VAUGHN:
18	BY MR. VAUGHN:	18	Q. Hello, Doctor.
19	Q. Cancer aside, I just want to talk	19	A. Hello.
20	about liver damage real quick, is it your	20	Q. You're a gastroenterologist,
21	opinion that NDMA cannot cause liver damage in	21	correct?
22	humans?	22	A. Yes, I am a gastroenterologist, but
23	MS. ROSE: Object to the form.	23	also a transplant hepatologist.
24	THE WITNESS: Yes. So I think my	24	Q. So you are a hepatologist as well,
25	opinion is that there is no well-founded	25	correct?
	Page 71		Page 73
1	scientific literature that demonstrate	1	A. Correct.
2	that NDMA-contaminated Valsartan	2	Q. Okay. And in practice is that what
3	certainly, there is nothing that really	3	you're doing is transplant hepatology?
4	definitely links that in humans with	4	A. Yes. That's my primary practice.
5		l	
	respect to liver damage, no. I think that	5	Q. And you are not an oncologist,
6	comes from primarily the animal	5 6	Q. And you are not an oncologist, correct?
	comes from primarily the animal literature.	6 7	Q. And you are not an oncologist,correct?A. Correct, I'm not an oncologist.
6 7 8	comes from primarily the animal	6	Q. And you are not an oncologist,correct?A. Correct, I'm not an oncologist.Q. Do you diagnose cancer?
6 7 8 9	comes from primarily the animal literature. BY MR. VAUGHN: Q. Sorry. Just a moment.	6 7	 Q. And you are not an oncologist, correct? A. Correct, I'm not an oncologist. Q. Do you diagnose cancer? A. Yes.
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6 7 8 9 10	comes from primarily the animal literature. BY MR. VAUGHN: Q. Sorry. Just a moment. Setting the Valsartan aside, just	6 7 8 9 10	 Q. And you are not an oncologist, correct? A. Correct, I'm not an oncologist. Q. Do you diagnose cancer? A. Yes. Q. And is that once they come to you
6 7 8 9 10 11	comes from primarily the animal literature. BY MR. VAUGHN: Q. Sorry. Just a moment. Setting the Valsartan aside, just NDMA, is it your opinion that NDMA itself	6 7 8 9 10 11	 Q. And you are not an oncologist, correct? A. Correct, I'm not an oncologist. Q. Do you diagnose cancer? A. Yes. Q. And is that once they come to you or in what setting are you diagnosing
6 7 8 9 10 11 12	comes from primarily the animal literature. BY MR. VAUGHN: Q. Sorry. Just a moment. Setting the Valsartan aside, just NDMA, is it your opinion that NDMA itself cannot cause liver damage in humans? A. Yeah. I mean, I haven't come across any, like I said, high quality	6 7 8 9 10 11 12	 Q. And you are not an oncologist, correct? A. Correct, I'm not an oncologist. Q. Do you diagnose cancer? A. Yes. Q. And is that once they come to you or in what setting are you diagnosing cancer?
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	D 71			D 76
1	Page 74 I diagnose cancers in the course of	1	there, I will look at the MRI. I will	Page 76
2	my routine care of my patients because every	2	kind of make my own assessment of, you	
	patient with cirrhosis, we have to screen them	3	know, is this concerning for	
3	for liver cancer. So I am the one who is	4	hepatocellular carcinoma or not.	
		5	*	
5	ordering their cancer screening studies,		But, of course, I will rely on the	
6	ultrasounds, alpha-fetoprotein, CT scans, MRIs	6	diagnostic radiologist's read. And	
7	if necessary. I am the one who is following up	7	usually the diagnostic radiologist will be	
8	on those images to to determine if there's	8	able to make a very clear assessment of	
9	something concerning or not who's then doing	9	the likelihood that this is, in fact,	
10	the additional work-up.	10	hepatocellular carcinoma by applying the	
11	And then I I work at a	11	LI-RADS criteria, and that is usually	
12	transplant center, so I participate in	12	sufficient.	
13	multidisciplinary tumor boards. So if I find	13	If if there's a LI-RADS 5	
14	something on an MRI that's concerning for liver	14	lesion, which is basically that's	
15	cancer in a patient with cirrhosis, I will I	15	regarding to be diagnostic of	
16	will bring that case to our multidisciplinary	16	hepatocellular carcinoma, that diagnosis,	
17	tumor board to review it with the radiologist,	17	I I would already been aware of when I	
18	the surgeons, other hepatologists, and medical	18	bring the case to the tumor board.	
19	oncologists who take care of these patients to	19	So the tumor board, sure, we're all	
20	confirm the diagnosis, make a treatment plan.	20	confirming that as a board, we agree that	
21	These things are usually done in a	21	there's hepatocellular carcinoma; but I'm	
22	multidisciplinary setting, but I am the	22	not relying on the hemato-oncologists, for	
23	primary, you know, provider that is responsible	23	instance, to make the diagnosis.	
24	for screening for it and then diagnosing the	24	The diagnosis is usually made if	
25	cancer, hepatocellular carcinoma, and other	25	it's a LI-RADS 5. It's more about	
	Page 75			Page 77
1	liver cancers in these patients.	1	thinking about the next steps, what the	
2	Q. Does there have to be a	2	best way to treat the patient; and that	
3	confirmation diagnosis when you make a	3	requires multidisciplinary discussion.	
4	diagnosis of cancer?	4	I would say that there are also	
5	A. I'm not entirely sure as to what	5	more borderline cases, like if it's a	
6	you mean by "confirmation diagnosis." Maybe	6	LI-RADS 3 or a LI-RADS 4, that is not	
7	you could clarify.	7	independently diagnostic of hepatocellular	•
8	Q. You said you take it to a when	8	carcinoma. And so we we still may	
9	you diagnose someone with cancer, you take it	9	review those images in the tumor board	
10	to a multidisciplinary board; and then a	10	just to agree upon a surveillance	
11	medical oncologist confirms the diagnosis.	11	strategy, for instance.	
12	Is that always the case, that	12	BY MR. VAUGHN:	
13	someone else is going to confirm your cancer	13	Q. And if you think there's cancer and	
14	diagnosis?	14	someone on the tumor board says that there's	
15	MS. ROSE: Object to the form.	15	not cancer, such as the oncologist, which	
16	Misstates the witness's testimony.	16	opinion trumps?	
17	THE WITNESS: No. I wouldn't	17	A. So in that instance where there's	
18	summarize it that way. Maybe I can	18	disagreement about whether or not a cancer is	S
19	clarify. I order the studies that would	19	present, that might arise, let's say, in	
20	di would be relevant to diagnose a	20	it's a pretty rare circumstance.	
21	potential hepatocellular carcinoma, for	21	Most of the time, I think, we're a	
22	instance. And I will look at the images	22	little bit differential to the diagnostic	
23	myself.	23	radiologist who has the most expertise in	
24	Let's say that if there's a patient	24	interpreting the cross-sectional images because	se
25	that needs an MRI and there is a mass	25	it's it's their dedicated expertise.	-
	and noods an ivita and more to a mass		to their addicated expertise.	

1	Page 78	1	Page 80
1	So if the radiologist is very	1	diagnostic radiologists at at my
2	confident that something is a LI-RADS 5, we	2	institution. I think they're very good,
3	we accept that as the tumor board, you know,	3	and they have much more dedicated
4	that it's LI-RADS 5 lesion.	4	expertise in reviewing radiology than I
5	I can't think of a case where,	5	do. They do it day in and day out as
6	like, the medical oncologist is, you know,	6	their job.
7	disagreeing with the diagnostic radiology	7	So so yes. I mean, if they feel
8	expert about LI-RADS 5 lesion, but there are	8	strongly that that their read is
9	maybe some scenarios where it might be a	9	accurate and they can show me why, then
1	LI-RADS 4 and we have a discussion as a group	10	yes, I'll I'll agree with with what
11	about, you know, what is the urgency to try to	11	their opinion is.
12	confirm that this is or is not hepatocellular	12	BY MR. VAUGHN:
13	carcinoma.	13	Q. Do you agree that the oncologists
14	And so in that scenario, if there's	14	have more expertise than you do in diagnosing
15	disagreement, we may pursue biopsy to get	15	cancer?
16	further to really kind of get, as a gold	16	A. So that's a very broad statement.
17	standard, confirmation of the presence or	17	I mean, if I were just narrow that down to
18	absence of cancer.	18	hepatocellular carcinoma specifically, I would
19	Q. And you said you're not a	19	not uniformly agree with that because, like I
20	radiologist, but you do review the actual	20	said, the oncologists are usually not the ones
21	imaging, correct?	21	who are making the diagnosis. They're not the
22	A. Yes.	22	ones who are screening these patients for
23	Q. And in practice if the diagnostic	23	cancer.
24	radiologist disagreed with you, you would defer	24	The on medical oncologists in
25	to them?	25	the setting of hepatocellular carcinoma are
	Page 79		Page 81
1	MS. ROSE: Object to the form.	1	most often involved with more advanced
2	THE WITNESS: It would really	2	late-stage cancers because the medical
3	depend on the nature of the disagreement.	3	oncologists will be involved in administering
4	I mean, there have been scenarios where,	4	immunotherapy or sometimes systemic
5	you know, the initial diagnostic read	5	chemotherapy, things along those lines that are
6	that's reported, when I look at the	6	really treatments more for patients who have
7	imaging, I might identify something that I	7	very advanced disease.
8	am concerned about that I think might have	8	So in the setting specifically for
9	been missed in the radiology report; and		hepatocellular carcinoma, medical oncologists
10	then I'll have a discussion with the	10	are oftentimes involved very late in the
11	radiologist.	11	process, and they're they're usually not
12	And I can recall a couple of	12	they don't have a whole lot of primacy in the
13	scenarios where I've identified something	13	diagnosis. And the screening of hepatocellular
14	that I think was missed, and then I bring	14	carcinoma, that's usually the role of the
15	it to the radiologist. They re-review it	15	hepatologist.
16	and say, oh, okay, yes. Actually, in	16	Q. And is that because liver cancer is
17	retrospect, this does appear to be the	17	typically caught at earlier stages?
18	case; and they might amend their report.	18	MS. ROSE: Object to the form.
19	That does happen on occasion, but	19	THE WITNESS: We tried to sorry.
20	it's usually if there's a disagreement.	20	MS. ROSE: Go ahead, Doctor.
21	Or if I'm concerned about something, I'll	21	THE WITNESS: Apologies.
22	just have a conversation with them; and	22	Ideally, we identify patients that
23	we'll review it together.	23	require screening. So any patient with
24	But overall, yes. I I at the	24 25	cirrhosis, for instance, should enter a
25	end of the day, I primarily trust our	_23	surveillance pipeline for getting imaging

1	Page 82	1	Page 84 developing a liver cancer even within one year.
	and blood work every six months.	1	1 0
2	And the intention of that is to	2	So but they cancers, they
3	identify liver cancers early so that we	3	have different rates of growth. There's some
4	can treat it more effectively and		variation how fast a tumor can grow and thus be
5	hopefully cure it. Obviously there are	l .	detectable. I mean, sometimes you might have a
6	patients where, for for one reason or	l .	microscopic cancer that we don't see on
7	another, they're not identified as having	l	imaging, but it might be there; but it takes
8	cirrhosis or they don't complete their	8	some time for it to grow to the point where
9	surveillance appropriately, and then	l	it's actually observable microscopically on an
10	cancers may get diagnosed at a later	10	ultrasound or an MRI. But that's the best way
11	stage; but our our aspiration is to try	11	I can kind of frame the answer.
12	to catch them early.	12	Q. Do you have an opinion on if
13	BY MR. VAUGHN:	13	cirrhosis to go to HCC within six months?
14	Q. From the time that there's	14	MS. ROSE: Object to the form.
15	cirrhosis, how quickly can that turn to HCC?	15	THE WITNESS: So as I stated, I
16	A. So based on the established	16	mean, there are many patients that are
17	literature, you know, and, you know, national	17	simultaneously diagnosed with cirrhosis
18	and international hepatology society	18	and HCC, and I do think that a patient
19	guidelines, our best estimates are that there's	19	with cirrhosis that's let's say a
20	an annual risk of somewhere in the range of 1	20	patient's diagnosed with cirrhosis. Could
21	to 8 percent depending on the specific cohort	21	they have an HCC six months later?
22	or etiology of liver disease you're looking at.	22	Absolutely.
23	It's it's somewhere in that range.	23	And the reason I say that is
24	I think Dr. Siddiqui in her report	24	because it's possible to have an HCC even
25	acknowledged 2 to 4 percent annual incidence of	25	in the absence of cirrhosis, especially in
	Page 83		Page 85
1	HCC in those patients, which I generally agree	1	patients who have MASLD and MASH. It's
2	with. It's somewhere in that ballpark.	2	very well demonstrated in the literature
3	Q. And so you're talking annual	3	that that patients have a real risk of
4	incidence, and my question's a little	4	developing an HCC even before their
5	different.	5	degreeing their degree of scarring has
6	From the first time that they have	6	progressed to cirrhosis.
7	cirrhosis, how quickly can that cirrhosis turn	7	BY MR. VAUGHN:
8	to HCC?	8	Q. And so the diagnosis of HCC
9	A. So it's it's hard to it's	9	wouldn't actually support that someone has
10	I mean, it there are many patients who are	10	cirrhosis alone, correct?
11	diagnosed simultaneously with cirrhosis and	11	A. There's a very high likelihood that
12	HCC. I can really only frame it to you in	12	the patient will will would have
13	terms of annual risk.	13	cirrhosis. I think somewhere in the ballpark
14	You know, 2 to 4 percent of	14	of 80 percent of patients who have an HCC have
15	patients will develop a liver cancer within a	15	underlying cirrhosis; but no, it's not a
16	year of having cirrhosis. So it can happen	16	guarantee that if the only you looked at was
17	relatively quickly. It can happen on the time	17	the HCC, it ' not a guarantee that they have
18	course of a year, but it varies depending on	18	cirrhosis, no.
19	the patient, the the cause of the liver	19	Q. So you can't say, hey, this person
20	disease, and based on some type factors that we	20	has HCC, therefore, they have cirrhosis,
21	don't fully understand. But I can tell you	21	correct?
22	that that's the rate.	22	A. No, you can't say that. You'd have
23	And because of that, we screen all	23	to look at you'd have to do an assessment to
24	patients with cirrhosis for liver cancer	24	see if they actually have cirrhosis or not.
	because they all have a very high risk of	25	Q. And how do you do that assessment?
	occause they an have a very high list of		Z. And now do you do that assessment:

1	D 06		P. 00
1	Page 86	1	Page 88
$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	A. It's a good question. So there there's there are a lot of factors that come	1	it really pushes me in the direction of
		2	cirrhosis; but generally speaking, I'm
3	into consideration; but broadly speaking, there	3	looking at labs, including the AST, the
4	are imaging features that we look for. There	4	ALT, the platelet count. I'm looking at
5	are features on blood work. There are	5	the patient age.
6	prediction scores that we calculate from blood	6	Those those four things together
7	work and patient age.	7	are used to compute prediction score
8	And sometimes if there's really	8	called the FIB-4 score or the fibrosis-4
9	advanced cirrhosis, you would may expect	9	score, which is it's codified in our
10	certain clinical symptoms or clinical signs;	10	guidelines that this is a a screening
11	but usually it's a composite of these different	11	tool that we use in patients to stratify
12	data points.	12	individuals into different probabilities
13	You try to assimilate some	13	of risk of having significant scar in the
14	laboratory prediction modeling data points and	14	liver, advanced fibrosis or cirrhosis,
15	imaging data points to come to an assessment.	15	or or essentially, you know, minimal
16	Q. So you would agree it's not imaging	16	scar in the liver or something in between.
17	alone that you diagnose cirrhosis?	17	So we compute that for all
18	MS. ROSE: Object to the form.	18	patients, you know, that have, you know,
19	THE WITNESS: Sorry.	19	chronic liver disease, such as MASLD or
20	MS. ROSE: Go ahead. Sorry.	20	MASH as an initial assessment; but those
21	THE WITNESS: I wouldn't agree with	21	are some important labs.
22	it quite in that fashion because in some	22	Other labs that I look at that are
23	patients you you really can't make the	23	important are so-called liver synthetic
24	diagnosis.	24	function markers. So in addition to
25	I mean, so, for instance, if you	25	platelet count, that's also albumin. It's
	Page 87		Page 89
1	were to see, you know, multiple high	1	also INR that are important liver
2	probability features on a CT scan that	2	synthetic function markers, and bilirubin.
3	are that are, you know, that come with	3	BY MR. VAUGHN:
4	cirrhosis, you can generally make that	4	Q. Why are those three important
5	diagnosis.	5	albumin, INR, and bilirubin when it comes to
6	But let's say that you only saw one	6	
7		_	liver function?
1	suggested imaging feature of cirrhosis. I	7	A. So your liver has a lot of
8	personally don't rely on that alone. I	8	A. So your liver has a lot of important roles in your body. My view, it's
9	personally don't rely on that alone. I I would look also to laboratory findings	8 9	A. So your liver has a lot of important roles in your body. My view, it's the most important organ as a biased
9 10	personally don't rely on that alone. I I would look also to laboratory findings and and laboratory-based prediction	8 9 10	A. So your liver has a lot of important roles in your body. My view, it's the most important organ as a biased hepatologist.
9 10 11	personally don't rely on that alone. I I would look also to laboratory findings and and laboratory-based prediction models to add another data point to try to	8 9 10 11	A. So your liver has a lot of important roles in your body. My view, it's the most important organ as a biased hepatologist. But one of the among the things
9 10 11 12	personally don't rely on that alone. I I would look also to laboratory findings and and laboratory-based prediction models to add another data point to try to make the assessment.	8 9 10 11 12	A. So your liver has a lot of important roles in your body. My view, it's the most important organ as a biased hepatologist. But one of the among the things it does is it's a it's a major manufacturing
9 10 11 12 13	personally don't rely on that alone. I I would look also to laboratory findings and and laboratory-based prediction models to add another data point to try to make the assessment. BY MR. VAUGHN:	8 9 10 11 12 13	A. So your liver has a lot of important roles in your body. My view, it's the most important organ as a biased hepatologist. But one of the among the things it does is it's a it's a major manufacturing hub for proteins in your body as well as
9 10 11 12 13 14	personally don't rely on that alone. I I would look also to laboratory findings and and laboratory-based prediction models to add another data point to try to make the assessment. BY MR. VAUGHN: Q. And what labs are you looking for	8 9 10 11 12 13 14	A. So your liver has a lot of important roles in your body. My view, it's the most important organ as a biased hepatologist. But one of the among the things it does is it's a it's a major manufacturing hub for proteins in your body as well as clotting factors.
9 10 11 12 13 14 15	personally don't rely on that alone. I I would look also to laboratory findings and and laboratory-based prediction models to add another data point to try to make the assessment. BY MR. VAUGHN: Q. And what labs are you looking for to make that assessment of cirrhosis?	8 9 10 11 12 13 14 15	A. So your liver has a lot of important roles in your body. My view, it's the most important organ as a biased hepatologist. But one of the among the things it does is it's a it's a major manufacturing hub for proteins in your body as well as clotting factors. So albumin is the is the major
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	Page 90		Page 92
1	A sim a similar principle	1	cirrhosis, that can, to some extent, be
2	applies INR, which is a clotting factor marker.	2	
3	It's a measure of kind of production of	3	supplementation.
4	clotting factors. Some some, but not all,	4	So so like I said, there's
5	clotting factors are produced in the liver. So	5	nuance in interpreting these things, and you
6	if there's cirrhosis, as it gets more advanced,	6	have to interpret it in a particular patient
7	the INR may become abnormal.	7	context.
8	And the directionality's different.	8	Q. You were talking about if it was
9	The INR actually goes up as as cirrhosis	9	abnormal. I'm talking about if all of those
l	worsens over time; whereas, the albumin goes	10	are normal.
11	down. But that's usually the general	11	If all of those labs are normal,
12	significance.	12	does that mean they do not have advanced
13	The bilirubin tends to become	13	cirrhosis?
14	elevated usually only in very, very late stages	14	A. If they're all normal and, in
15	of cirrhosis, really advanced decompensated	15	particular, like, looking the trends, like, I
16	cirrhosis most of the time.	16	don't like to rely on, like, an isolated lab
17	Q. And so would you agree that	17	trend because sometimes there can be temporary
18	typically if the albumin and INR and bilirubin	18	or acute changes that cause things to
19	are normal, the patient does not have advanced	19	fluctuate; but I would say it makes it less
20	cirrhosis?	20	likely. I would agree it makes it less likely.
21	MS. ROSE: Object to the form.	21	If those things are all normal, it's less
22	THE WITNESS: I would not uniformly	22	likely that the patient would have very, very
23	agree to that. There's a lot of nuance	23	advanced cirrhosis, yes.
24	that goes into interpreting these labs.	24	Q. And did you review the labs,
25	I would say in general, patients	25	albumin, INR, and bilirubin in Mr. Roberts'
	Page 91		Page 93
1	with advanced decompensated cirrhosis, you	1	
2	do expect to see progressive derangements	2	A. I did. But I should emphasize one
3	in those labs. But the issue is that	3	other thing that you know, the other
4	those labs can be altered for other issues	4	important lab that I think you're leaving out
5	oftentimes unrelated to liver disease.	5	is platelet count. And that's actually also
6	So you have to interpret all all	6	another one of these synthetic function markers
7	of this in the context of the particular	7	that's that's very critical to highlight as
8	patient.	8	well.
9	But the general trends I	9	So that's I would throw that in
10	articulated to you are things you see as	10	the bucket of important labs to assess when
11	cirrhosis becomes more advanced; but it's	11	you're looking at progression of liver disease
12	important to highlight that even if those	12	and cirrhosis.
13	are normal, it does not rule out the	13	So yes, I did review these labs for
14	presence of cirrhosis.	14	Mr. Roberts, including his, you know,
15	BY MR. VAUGHN:	15	transaminases, his FIB-4 over time, and his
16	Q. Would it rule out the presence of	16	platelet count over time.
17	advanced cirrhosis?	17	Q. But for advanced cirrhosis, you 'e
18	A. Not necessarily. I I wouldn't	18	looking at more at the albumin, INR, and
19	say that either. So for instance, it's very	19	bilirubin, correct?
20	common for patients to be on a blood thinner,	20	MS. ROSE: Object to the form.
21	and the blood thinner can make the INR	21	THE WITNESS: No. I'm looking at
22	abnormal. And so we then can't rely on the INR	22	the composite of these labs, and I'm
23	as a marker of synthetic function.	23	I'm also very carefully looking at the
7)1	Likewise, some of the albumin	24	platelet count. The platelet count is
24 25	reduction that can happen over time in	25	actually a very, very important marker of

1		ge 94	1	Page 96
$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	progression of cirrhosis between stages		1 2	finding.
3	between stages of compensated and decompensated cirrhosis.		3	Q. And why is that in Mr. Roberts' case?
4	The platelet count is a very, very		4	
5	important marker of something called		5	A. I'd say there's there are are two important contributors of the platelet
6	portal hypertension. It's elevated		6	count that come to mind in his case. One, it's
7	pressures kind of, you know, behind the		7	a component in that FIB-4 calculation. I
8	liver in the large vein that's flowing		8	forget if I gave you the whole formula, but
9	into the liver.		9	it it involves the AST, the ALT, the
10	And the full hypertension the		10	platelet counts, and the age. So all of those
11	blood pressure in this portal system		11	components go into an assessment of the
12	begins to climb as patient's severity of		12	likelihood of cirrhosis. So that that
13	cirrhosis increases. And the platelet		13	hopefully articulates why the platelet count is
14	count will begin to decrease gradually as		14	an independent important marker of the
15	that gets worse.		15	likelihood of cirrhosis.
16	So that is oftentimes a very early		16	But in reviewing Mr. Roberts
17	indicator that a patient's progressing to		17	records, you know, his platelet count used to
18	more advanced cirrhosis.		18	be normal; and then it gradually began to
19	BY MR. VAUGHN:		19	decline.
20	Q. How low of a platelet count would		20	I'm sorry. I'm pulling up my
21	you anticipate for advanced cirrhosis?		21	report to just look at the timeline in case
22	MS. ROSE: Object to the form.		22	that becomes relevant. But off the top of my
23	THE WITNESS: There's a lot of		23	head, I remember very specifically his, I
24	variability in patients, so I can't give		24	think, primary care physician Dr. Sanders. He
25	you, like, a a concrete cutpoint		25	noted on on multiple occasions and during
	<u> </u>	05		-
1	because oftentimes you're looking at the	ge 95	1	Page 97 their visits that the platelet count had become
2	trend.			low, and he did not understand why. But that
3	I'll say as a general marker, a		3	it used to be normal.
4	platelet count of less than 150 is		4	So Dr. Sanders had identified that
5	regarded to be abnormal. That's		5	as an unusual finding which I think with the
6	abnormally low. That's the definition of		6	
7	thrombocytopenia, which just means low		7	record, I recognize that is clearly an
8	platelet count. But the trend is		8	indicator that Mr. Roberts had developed
9	important.		9	cirrhosis that was becoming more advanced. But
10	So I mean, if someone's baseline is		10	that's why it was very relevant.
11	300 and it's been 300 for years and years		11	He used to have normal platelet
12	and then over the past year, I see it's		12	count, and then it trended down during the
13	gone down from 300 to 250 to 200 to 155,		13	course of his medical course, which I viewed to
14	that 'a concerning trend even though it's		14	be consistent with his diagnosis of cirrhosis.
15	still technically above this threshold of		15	Q. You say you were looking at the
16	less than 150.		16	timeline on this.
17	If a platelet count used to be		17	What was the first date that he was
18	normal and is now less than 150, that's		18	actually diagnosed with thrombocytopenia?
19	very concerning to me in a patient that		19	A. I'm sorry. Let me just pull up my
20	I'm worried about cirrhosis.		20	report. Sorry. Bear with me. I've got my
21	BY MR. VAUGHN:		21	medical timeline here up now. All right.
22	Q. Would you consider the platelets		22	I did try to note down in my review
23	one of the most important lab findings for		23	of his record where I saw platelet counts and
24	Mr. Roberts in coming to your conclusions?		24	tried to note that where it was relevant.
25	A. Yes, it's a very important lab		25	So let's see. In 2009 it was 174,
I	· •			

1	Page 98 so it was not in the range that I would say is	1	Page 100 in in a laboratory that runs, you know,
$\frac{1}{2}$	thrombocytopenia at that time. In okay. So	$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	these these tests myself, no.
$\begin{vmatrix} 2 \\ 3 \end{vmatrix}$	in November, November 4th, 2015, his platelet	$\frac{2}{3}$	Q. Do you know how they set their
4	count was 137. That is thrombocytopenia.	4	reference ranges?
5	Q. Was he	5	A. I have an understanding for it
6	A. That is abnormally low.	6	may vary by from lab to lab, but I have a
7	Q. Was he diagnosed with	7	general sense of how these are set. And I
8	thrombocytopenia at that point?	8	actually know this specifically for things like
9	A. The the definition of	9	transaminases because understanding the
10	thrombocytopenia is the lab value. So I don't	10	methodology for that comes from is an important
11	know if any particular physician directly	11	lesson for why us as hepatologists have our own
12	said you know, I don't know if any of his	12	set of understood normal versus abnormal
13	treating physicians articulated it at that	13	ranges.
14	time, but that value is the definition of	14	So just I'll be very concise. AST
15	thrombocytopenia. He had thrombocytopenia on	15	and ALT, there are normal ranges that are very
16	that date at that time.	16	commonly reported. Let's say ALT. You might
17	Q. Are you a hematologist?	17	see a lab that says, you know, up to an ALT of
18	A. I'm not a hematologist.	18	39 might be normal. To a hepatologist an ALT
19	Q. Do you order labs?	19	of 39 is abnormal.
20	A. I order labs all the time, yes.	20	The reason why it's why we we
21	Q. Do you read labs?	21	have why we say this is when they determine
22	A. I read labs all the time.	22	reference ranges for transaminases, oftentimes
23	Q. How do you know if the labs are out	23	these were were were done by taking
24	of range?	24	individuals from the population that were
25	A. Well, so it's generally a normal	25	taught to be healthy. They measured their
		_	
	Page 99		Page 101
1	Page 99 range is reported by by a particular lab,	1	Page 101 labs. You get a bell curve. You get a bell
1 2		1 2	
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24 the VA sometimes, and sometimes they'll get 24 MS. ROSE: Okay. Thanks.	23		23	-
	24		24	MS. ROSE: Okay. Thanks.
25 labs done outside at Labcorp or 25 THE VIDEOGRAPHER: We're off the	25		25	-

1	Page 106 record at 10:56.	1	Page 108 A. Yeah. This lists many things that
2	(Whereupon, a break was taken.)	2	A. Yeah. This lists many things that cause cirrhosis. And It also lists many
3	THE VIDEOGRAPHER: We are back on	3	complications of cirrhosis, you know, for
4	the record at 11:03 a.m.	4	instance, things like ascites, esophageal
5	BY MR. VAUGHN:	5	varices, liver cancer, as well, you know, the
6	Q. All right. Doctor, sorry about	6	relevant therapies that are used for cirrhosis
7	that.	7	like liver transplantation. I believe those
8	A. That's okay. No problem.	8	are all listed here.
9	Q. All right. So I have that web page	9	Q. You know that cirrhosis can cause
10	now as an exhibit. This will be Exhibit 3. It	10	liver cancer.
11	should also be dropped if you need to look at	11	Can it go the other way as well?
12	it as the full exhibit.	12	Can liver cancer cause cirrhosis?
13	(Whereupon, Exhibit 3,	13	A. No. No. HCC does not cause
14	PennMedicine.org profile of Nadim	14	cirrhosis.
15	Mahmud, MD, MS, MPH, MSCE, was marked for		Q. And why is that?
16	identification.)	16	A. So essentially, cirrhosis is a
17	BY MR. VAUGHN:	17	state where there is a significant amount of
18	Q. And all right. And earlier I was	18	scarring, you know, typically throughout the
19	talking about where it says "liver cancer."	19	liver that results from chronic inflammation.
20	And so it doesn't say HCC, but you	20	And so the the understood, you
21	agree that liver cancer is essentially	21	know, risk factors, you know, for this are
22	synonymous with HCC?	22	things like alcohol-related liver disease,
23	MS. ROSE: Object to the form.	23	MASLD and MASH, Hepatitis C. Those things
24	THE WITNESS: I would say that HCC	24	cause chronic inflammation in the liver.
25	is a type of liver cancer. My expertise	25	Chronic inflammation leads to scar tissue
	Page 107		Page 109
1	in liver cancer extends beyond the HCC.	1	formation. And then once a sufficient amount
2	It includes other types of liver cancers.	2	of scar accumulates, that's you know, to the
3	For example, bile duct cancers like	3	point where it's affecting the liver function
4	cholangiocarcinoma.	4	in some regard, that's that's cirrhosis.
5	BY MR. VAUGHN:	5	HCC does not cause inflammation
6	Q. And so then cirrhosis is not listed	6	throughout the liver like a chronic liver
7	on here, is it?	7	disease does, nor does it induce scarring of
8	A. I'm looking through here. It's	8	the, you know, throughout the liver, like a
9	liver failure I think, you know, is	9	form of chronic liver disease does.
10	encompassing, you know, aspects of, you know,	10	I mean, I'm not aware of any
11	the progression of chronic liver disease to	11	literature that that, you know, that kind of
12	to, you know, up to and including cirrhosis.	12	identifies HCC, for instance, as a causal
13	Q. Okay.	13	factor for cirrhosis. I've never come across
14	A. And I'm sorry to interrupt. But	14	that.
15	and also, you know, while the word "cirrhosis"	15	The only I guess the only
16	may not be literally written out here, all of	16	scenario where I could see something along the
17	the you know, many of the relevant liver	17	lines of cirrhosis being imputed for someone
18	diseases are detailed here for expertise, like,	18	with a history of HCC is a condition called
19	alcoholic liver disease, autoimmune hepatitis,	19	pseudocirrhosis where someone who has very
20	Hepatitis C, et cetera. These are all things	20	diffuse HCC in the liver that has been treated
21	that cause chronic liver disease and cirrhosis.	21	many times with different local regional
22	So that I use that as a clarifying	22	therapies to the point where the liver has
23 24	point. O And so this lists many things that	23	taken a lot of damage from the treatments, you
25	Q. And so this lists many things that can cause cirrhosis?	24 25	can sometimes get a liver that begins to behave as if there is cirrhosis, and that's called
L ²³	Can Cause Chimosis;		as it there is cittiosis, and that's called

	Page 110		Page 112
1	pseudocirrhosis. But that's that's a unique	1	
2	case and and not what is typically meant	2	Q. Is hepatic fibrosis, is that
3	when when someone says does liver does	3	synonymous with cirrhosis, or is there a
4	liver cancer cause cirrhosis.	4	distinction there?
5	Q. And so cirrhosis is caused by	5	A. Yeah. Thanks for the question. So
6	inflammation in the liver?	6	I'll clarify that.
7	A. Yeah. That's that's understood	7	Fibrosis is just a medical word
8	to be the pathway. It's things that cause	8	that means scar. So fibrosis by itself is not
9	chronic inflammation throughout the liver.	9	synonymous with cirrhosis. You could have a
10	That leads to scar tissue accumulation over	10	mild amount of scar, or you can have a very
11	time, and the amount of scar tissue goes	11	advanced degree of scar.
12	through different stages that are usually	12	So when if there's very advanced
13	defined based on biopsies.	13	fibrosis, you know, to to a certain degree,
14	And if there's a sufficient amount	14	that that then at some point becomes
15	of scar tissue and you see certain features on	15	cirrhosis. But the term itself does not
16	a biopsy that would be diagnostic of cirrhosis	16	does not mean cirrhosis.
17	if you were to look at biopsies. I mean, these	17	Q. Can you have advanced fibrosis and
18	days we don't need to rely on biopsies because	18	still not have cirrhosis?
19	we have very well-validated ways of identifying	19	A. Yes, you can. Advanced fibrosis,
20	cirrhosis just based on labs, imaging,	20	the way and I admit this is used differently
21	prediction models, et cetera.	21	in different literature, but most hepatologists
22	Q. So it's your opinion that HCC does	22	when we use the term "advanced fibrosis," we
23	not cause inflammation within the liver?	23	are referring to two very specific stages of
24	A. I mean, it's possible that, you	24	fibrosis.
25	know, with HCC there may be some localized	25	So just to be very clear about
1	Page 111	1	Page 113
1	inflammation potentially around the the	1	that, there there generally there are
2	inflammation potentially around the the tumor, but I you know, I I don't view HCC	2	that, there there generally there are four stages of fibrosis in the liver that go
2 3	inflammation potentially around the the tumor, but I you know, I I don't view HCC to be a very strongly inflammatory tumor.	2 3	that, there there generally there are four stages of fibrosis in the liver that go from F0 to F4. F0 is totally normal. There's
2 3 4	inflammation potentially around the the tumor, but I you know, I I don't view HCC to be a very strongly inflammatory tumor. I mean, I know that Dr. Siddiqui	2 3 4	that, there there generally there are four stages of fibrosis in the liver that go from F0 to F4. F0 is totally normal. There's no scar, normal healthy liver. F4 is
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1	Page 114	1	Page 116
1	attuned to this nuance, they potentially	1	Q. Okay. All right.
2	could use that term incorrectly.	2	And do you see on here it says,
3	BY MR. VAUGHN:	3	"Liver failure can also occur suddenly when the
4	Q. And in your practice, have you ever	4	body is exposed to toxins or poisonous
5	ran into like a radiologist that might use	5	substances that severely compromise liver
6	cirrhosis as opposed to advanced fibrosis?	6	function"?
7	MS. ROSE: Object to the form.	7	Do you agree with that?
8	THE WITNESS: In my experience	8	A. I agree with that in a very
9	radiologists, they will use the term	9	specific context.
10	cirrhosis. They they don't commonly	10	I can tell you exactly what that
11	use the term "advanced fibrosis" because	11	means actually. They're
12	the the signs that are observed on	12	Q. All right. Go ahead.
13	imaging like a CT scan or an ultrasound,	13	A. So yeah. So liver failure, what
14	those are those have been studied with	14	they're referring to here is acute liver
15	respect to cirrhosis not advanced	15	failure, which is different than cirrhosis.
16	fibrosis.	16	And the acute toxins that cause liver failure
17	So they're they're usually yo	17	are things like Tylenol, like acetaminophen, or
18	know, in my experience again, I can't	18	a particular type of mushroom, amanita
19	speak on behalf of all radiologists out	19	phalloides, or the the death cap mushroom.
20	there, but most I'd say well-qualified	20	These are substances that can cause a very
21	diagnostic body radiologists they frame	21	acute injury that causes widespread death of
22	things in terms of cirrhosis.	22	liver cells, but it's actually it's
23	BY MR. VAUGHN:	23	unrelated to cirrhosis.
24	Q. All right. And then on this web	24	It doesn't cause cirrhosis. It's
25	page down here, there's this Penn Liver	25	causing widespread death of cells. That
-	Page 115		Page 117
1	Diseases Program.	1	results in very abrupt failure of the liver
2	Are you part of the Penn Liver	2	that may require transplant.
3	Diseases Program?	3	So that's that's, you know, what
4	A. You'd have to click on that to show	4	that, I assume, is referring to as a
5	me what that exactly is.	5	hepatologist.
6	Q. Okay. And like right here it does	6	Q. Would widespread death of liver
7	say that you are a part of it, right?	7	cells result in cirrhosis?
8	Dr. Mahmud, is part of the Penn	8	A. Generally, no. So the medical term
	Liver Diseases Program.	_	is "hepatic necrosis." So, you know, if
10	MR. VAUGHN: Can you drop that one	10	somebody developed let's say somebody took a
11	· 1	11	bunch of Tylenol, a very, very high dose of
12	in, Kathryn? And that'll be Exhibit 4.	12	
		13	Tylenol. That can result in widespread hepatic cirrhosis liver death.
13	(Whereupon, Exhibit 4, Penn	_	
14	Medicine Liver Diseases Program, was	14	And if you did a biopsy of that
15	marked for identification.)	15	patient, you'd see that there's a lot of dead
16	MS. AVILA: Yes. It's in there.	16	liver cells. But the amazing thing is that
17	MR. VAUGHN: Thank you.	17	your a previously healthy liver has a very
18	THE WITNESS: All right. There it	18	high ability to regenerate.
19	is.	19	And so if the person survives the
20	Okay. I have it up.	20	acute liver failure episode, we would actually
21	BY MR. VAUGHN:	21	expect that patient to regenerate to the point
22	Q. There you go.	22	of having the more or less the same baseline
23	Is that shown on my screen too?	23	liver function that they had before taking all
24	Did that change over to the	24	the Tylenol.
25	A. Yes. I see it.	25	So no. It's it's a distinct

Page 118 Page 120 1 type of pathologic pathway where it doesn't --1 think do cause liver cancer in humans? 2 it doesn't typically result in cirrhosis 2 A. Yes. 3 independently, no. 3 Q. Okay. Can those --Q. It talks up here about liver 4 So you know, af- -- you know, for 5 problems can be genetically inherited, occurred 5 instance, aflatoxin, it's a type of microtoxin as a result of disease, or be caused by that, you know, again, I haven't re--environmental stressors. reviewed the data in great detail, you know, 8 What are environmental stressors? 8 recently; but that is something that, you know, 9 as hepatologists, we recognized as being A. Sorry. Which part did you 10 highlight? something that's associated pretty consistently 11 in different studies with -- with a risk of --11 I just wanted to make sure I see 12 of liver cancer in humans. 12 the right section. 13 Q. Well. It doesn't highlight well. 13 Q. Can you think of any other 14 Right here. carcinogens that cause liver cancer? 14 15 A. Liver problems -- biostressors. 15 A. So, you know, there's -- I can -- I 16 can list other ones that I've come across Yeah. So I think this is, you 16 17 know, most likely referring to -- you know, so 17 literature in the past. The strength of the 18 they're listing the common chronic liver literature I -- I can't immediately comment on. diseases, you know, in the section below, you But other exposures that -- that I've seen, 19 20 know, Hepatitis B, C, et cetera. there is some association with -- sorry, 20 21 There are many different 21 androgen exposure. 22 environmental stressors that different 22 So particular types of androgen 23 individuals may be subjected to. 23 preparations, like testosterone types of 24 You know, NAFLD, which is an 24 preparations in a particular route of 25 outdated term now, but, you know NAFLD or -- or administration. There is some limited evidence Page 119 Page 121 1 that -- that can be associated with 1 MASLD or MASH, nonalcohol-related fatty liver disease, just to put it more colloquially, can 2 hepatocellular carcinoma in humans. 3 be regarded to be environmental stressors. I think there's also some very 3 4 It's -- it's related to -- to 4 limited data about maybe benzene exposure and 5 dietary exposures. It's much more common in some aromatic compounds. But honestly, there 6 the United States to see MASLD and MASH than are not that many major carcinogens that come to mind that have been linked -- you know, I 7 in -- in some other countries because we have 8 very particular dietary exposures. think aflatoxin is the one that comes to mind 9 Alcohol is an environmental stress as being one where there might be a little bit 10 or in an environmental stressor, and 10 more evidence. 11 environmental factor that is very relevant to 11 But for each of these, I would have 12 liver disease and cirrhosis in a lot of 12 to review the strength of evidence in more detail to make an assessment of -- of how 13 patients. relevant they are in humans. I'll say that all 14 So I'd say those are probably the 15 most two predominant relevant ones that 15 of these things are exceptionally rare 16 contribute to cirrhosis in the United States. 16 exposures. Would carcinogens fall under 17 17 And does that prevent them from 18 environmental stressors? 18 being studies of -- studied as much because 19 A. I -- I think if there was some 19 it's such rare to be supposed? 20 carcinogen that was well-demonstrated to -- to 20 MS. ROSE: Object to the form. THE WITNESS: Not necessarily. I cause cirrhosis and cirrhosis comp---21 22 complications, you could regard that to be a 22 think, you know, many -- many things can 23 relevant environmental stressor, sure. 23 be studied using observational studies; 24 and whether or not, you know, a research 24 Q. Excuse me.

group chooses to spend time researching

25

Are there any carcinogens that you

25

	Page 122		Page 124
1	something is oftentimes based, first, on	1	summary.
2	animal studies. Is there anything	2	Q. And for for the layperson, it
3	potentially relevant to humans to justify	3	would be two things, the scarring of the liver
4	doing a study.	4	plus the poor liver function to have cirrhosis,
5	You know, my recollection is that	5	correct?
6	there are studies for for each of the	6	MS. ROSE: Object to the form.
7	things I mentioned, but I you know, I	7	THE WITNESS: Yes. So I mean, I
8	can't I can't speak to the strength of	8	I disagree a little bit with the
9	them off the top of my head. I'd have to	9	characterization there because, as I've
10	review them again.	10	stated before, you can have cirrhosis
1	BY MR. VAUGHN:	11	
11		l	without having clear evidence of
12	Q. Do you have an opinion if there's	12	derangement of liver synthetic function.
13	more literature or less literature on benzene	13	Oftentimes, that is seen later in the
14	causing liver cancer in humans than NDMA?	14	progression of cirrhosis.
15	MS. ROSE: Object to the form.	15	You know, perhaps again, I don't
16	THE WITNESS: No, I don't have an	16	know who makes this website or who's
17	opinion on that. I I haven't reviewed	17	responsible for the content, but, you
18	the literature with respect to benzene	18	know, I'm not responsible. I I
19	inasmuch depth as I have with NDMA as	19	don't I don't write this myself. You
20	pertain pertaining to this case.	20	know, Penn Medicine I have no idea who
21	But I do recall that there are some	21	actually writes this.
22	studies. I can't speak to the volume or	22	But I I assume it's filtered
23	depth of them.	23	through a lens to make this very
24	BY MR. VAUGHN:	24	simplistic for patients to just broadly
25	Q. Okay. And then on this web page we	25	understand what cirrhosis often means.
	Page 123		Page 125
1	were on, it has common liver diseases; and it	1	And so yes, it means scarring of
2	has cirrhosis as a link.	2	the liver, and it can mean poor liver
3	MR. VAUGHN: If you'd go ahead and	3	function; but as I've stated previously,
4	drop the cirrhosis one, Kathryn, that will	4	you can have cirrhosis and actually have
5	be Exhibit 5.	5	relatively reserved liver synthetic
6	(Whereupon, Exhibit 5, Penn	6	markers on your blood work.
7	Medicine Cirrhosis - Symptoms and Causes,	7	BY MR. VAUGHN:
8	was marked for identification.)	8	Q. And so do you disagree with the
9	MS. AVILA: Okay. It should be in	9	information that Penn Medical is putting out to
10	there.	10	the public?
11	MR. VAUGHN: Okay.	11	MS. ROSE: Object to the form.
12	BY MR. VAUGHN:	12	THE WITNESS: Like I said, I think
13	Q. And for the definition of	13	that my my understanding and nuanced
14	cirrhosis is scarring of the liver and poor	14	understanding of cirrhosis as a clinician
15	liver function.	15	goes much more beyond what, you know, this
16	Do you agree with that definition	16	website is communicating to patients.
17	of cirrhosis?	17	I think that, likely, they're
18	A. I I think it's a very, probably,	18	trying to keep things very simple to
19	oversimplified definition of cirrhosis for the	19	provide at a high level, you know, some
20	purpose of the lay public.	20	understanding of what these medical terms
21	I think I've already given you my	21	may generally mean.
22	definition of cirrhosis, but, you know, I think	22	I don't think their intention is
23	for for simplicity and communicating it to a	23	likely to be extremely detailed about the
24	patient who might be visiting this website, I	24	technical definitions of cirrhosis.
25	think it's a it's a rudimentary layperson	25	
	anna ito a realimentary rayperson		

	D 444		B 400
1	Page 126 BY MR. VAUGHN:	1	Q. And Mr. Roberts wasn't experiencing
2	Q. So do you think it would be more	2	weight loss prior to 2018, correct?
3	accurate if it had the word "often" before poor	3	A. I'd have to review his records in
4	liver function: "Cirrhosis is scaring of the	4	detail, but my recollection is no. He was in
5	liver and 'often' poor liver function"?	5	the range of Class 2 obesity quite consistently
6	Would that be more accurate for	6	for much of his medical record history.
7	you?	7	Q. And Mr. Roberts didn't have fatigue
8	MS. ROSE: Object to the form.	8	or loss of energy prior to 2018, correct?
9	THE WITNESS: Again, like I I	9	A. You know, I I I don't recall
10	don't have a role in creating this website	10	that being mentioned specifically in in his
11	or curating it to a particular audience.	11	records. It's it's possible that he may
12	I think, you know, if if I were	12	have mentioned that as a symptom. You know, it
13	to to generate this myself,	13	may or may not have been codified by a
14	hypothetically, I probably would caveat it	14	clinician that was doing their summary.
15	in some fashion similar to that. It	15	But that did not come across as
16	doesn't have to be invariably associated	16	being a prominent symptom, you know, during
17	with, you know, poor liver function, but	17	during well, I think once he had cancer, I
18	it it often is as it progresses.	18	think he probably did express some of these
19	BY MR. VAUGHN:	19	things; but early in the medical record, I
20	Q. Okay. And symptoms, and those	20	don't think those were very consistent symptoms
21	symptoms are early symptoms are typically	21	that were documented.
22	fatigue and loss of energy energy.	22	Q. Were they ever documented?
23	Do you agree with that?	23	A. I'd have to review I'd have to
24	A. I don't uniformly agree with that.	24	review the records again to see if there's
25	That's not that is not uniformly seen. That	25	specific mentions of fatigue or loss of energy.
	D 107		
	Page 127		Page 129
1	can be seen with some particular etiologies of	1	Q. What about small red spiderlike
2	can be seen with some particular etiologies of chronic liver disease, but it is very common	2	Q. What about small red spiderlike blood vessels on the skin, did you see evidence
2 3	can be seen with some particular etiologies of chronic liver disease, but it is very common for someone to have cirrhosis that is	2 3	Q. What about small red spiderlike blood vessels on the skin, did you see evidence of that prior to his cancer diagnosis?
2 3 4	can be seen with some particular etiologies of chronic liver disease, but it is very common for someone to have cirrhosis that is compensated and have no symptoms really at all	2 3 4	Q. What about small red spiderlikeblood vessels on the skin, did you see evidenceof that prior to his cancer diagnosis?A. So that is a specific physical exam
2 3 4 5	can be seen with some particular etiologies of chronic liver disease, but it is very common for someone to have cirrhosis that is compensated and have no symptoms really at all from the patient perspective.	2 3 4 5	 Q. What about small red spiderlike blood vessels on the skin, did you see evidence of that prior to his cancer diagnosis? A. So that is a specific physical exam finding. There's telangiectasias that you can
2 3 4 5 6	can be seen with some particular etiologies of chronic liver disease, but it is very common for someone to have cirrhosis that is compensated and have no symptoms really at all from the patient perspective. Q. Okay. And so would you also	2 3 4 5 6	Q. What about small red spiderlike blood vessels on the skin, did you see evidence of that prior to his cancer diagnosis? A. So that is a specific physical exam finding. There's telangiectasias that you can see oftentimes in the upper chest on patients.
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1	Page 130	1	Page 132
	exam, but it doesn't guarantee that	1	an upper limit.
2	something was not present BY MR. VAUGHN:	2	I've I've heard some
3		3	radiologists say 13 centimeters, but there are
4	Q. Do you	4	also other ways to assess for an enlarged
5	A for any given patient.	5	spleen. There are ways of doing volume
6	Q. Do you plan to tell the jury that	6	calculations. Instead of relying on just one
7	Mr. Roberts might have had fatigue, loss of	7	axis, some radiologists will do a more detailed
8	energy, poor appetite, or weight loss or spider	8	assessment where they do measurements in three
9	red-like blood vessels of the skin prior to his	9	dimensions on a CT scan to compute a spleen
10	diagnosis of the cancer?	1	volume. And off the top of my head, I don't
11	MS. ROSE: Object to the form.	11	recall, you know, what the upper limit of
12	THE WITNESS: I plan to communicate	12	normal is for that.
13	very clearly that he had very clear	13	But when I did my my own
14	evidence of of a diagnosis that	14	independent review of the images, I did take
15	shouldn't have been made previously of	15	the time to do these measurements; and I did
16	cirrhosis that, you know, predated his		reference the upper limits of normal. Again, I
17	cancer diagnosis by by quite sometime.	17	don't recall the exact cutpoints for volume off
18	None of that really relies on the	18	the top of my head; but that was part of my
19	symptomatology. I make that assessment	19	process when I was evaluating that scan for
20	based on his imaging and blood work and	20	splenomegaly.
21	and the prediction scores that I mentioned	21	Q. What size was Mr. Roberts' spleen
22	primarily. It does not rely on his	22	when you looked at it in 2016?
23	<mark>symptoms</mark> .	23	A. I don't recall off the top of my
24	BY MR. VAUGHN:	24	head, but I you know, I I'm happy to re-
25	Q. Okay. Let me go down to exams and	25	review it and recalculate this if necessary.
	Page 131		Page 133
1	tests for cirrhosis on Penn's website.	1	But, you know, like I said, I I
2	Prior to 2016, did he have a or	2	had my impression based on my own read, but I'm
3	2018, did Mr. Roberts have an enlarged spleen?	3	very differential to a qualified radiologist to
4	A. Yes. In my view on his his	4	make the the assessment. And like I said, I
5	April let me pull up my report just to to	5	believe Dr. Mele and Dr. Chernyak both agree
6		5	
	give you the right date. I believe it was	6	that there is splenomegaly.
7	April 19. Let me just check real quick.		
7 8	April 19. Let me just check real quick. So on my review of his April 19th,	6	that there is splenomegaly. And so ultimately, I find their assessment is likely to be the most valid.
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8	April 19. Let me just check real quick. So on my review of his April 19th, 2016, CT scan, my impression is that he had an enlarged spleen; and I believe that was also	6 7 8	that there is splenomegaly. And so ultimately, I find their assessment is likely to be the most valid. But, you know, when I was going through the images myself, my own assessment was was
8 9 10 11	April 19. Let me just check real quick. So on my review of his April 19th, 2016, CT scan, my impression is that he had an enlarged spleen; and I believe that was also the impression of the expert radiologists in	6 7 8 9 10 11	that there is splenomegaly. And so ultimately, I find their assessment is likely to be the most valid. But, you know, when I was going through the images myself, my own assessment was was consistent with what they found.
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16 Q. And does it save the results? 17 A. I don't know if it does, actually, 18 I suspect it doesn't because every time I've 19 loaded up the B DICOM viewer, I have to 20 reimport all the images. So I don't think it 21 saves specific measurements that I – I've 22 taken. 23 Q. All right. And so — so you're not 24 sure if Mr. Roberts' spleen was just a half of 25 centimeter bigger? 26 massurement of thrombocytopenia previously, and 27 sure if Mr. Roberts' spleen was just a half of 28 centimeter bigger? 29 Taken. 20 Q. All right. And so — so you're not 29 sure if Mr. Roberts' spleen was just a half of 20 centimeter bigger? 20 AS. ROSE: Object to the form. 21 THE WITNESS: Like I said, I can't 22 give you the exact measurement in this 23 give you the exact measurement in this 24 moment. And — but, you know, I — I — 25 you know, if it — if it's even in 26 question, I would, again, defer to the 27 expert radiologists on both the 28 plaintiffs' and the defense side who 29 report that there is an enlarged spleen. 20 And you're aware that his treating 21 brysicians at the time did not diagnose him 22 with an enlarged spleen in 2016, correct? 23 his low platelet count. 24 Un happy to explain why it's relevant if — if 25 you like. I just wanted to find the date of 26 you like. I just wanted to find the date of 27 lim happy to explain why it's relevant if — if 28 you like. I just wanted to find the date of 29 like I just wanted to find the date of 20 Sorry. I'm planning to get to it 21 lot it now, you can. 22 A. Sure. That's okay. We can — we 23 nia na save it for later. 24 Q. Okay. Have you ever diagnosed an 25 enlarged spleen in practice? 26 A. So I guess you mean — it depends 27 what you mean by, like, have I ever diagnosed a 28 large spleen. 29 I — I definitely communicated a 29 diagnosis of a large spleen to patients. But 29 offentimes — you know, many aspects of 20 it is now, oposicians that have a role in — in 20 ascertaining a diagnosis. 21 would order imaging for a patient, an 22 ultrasound or a CT scan, whatever i	15		15	
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25 of gets back to prior point about the physical 25 to the patient.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	MS. ROSE: Object to the form. THE WITNESS: Like I said, I can't give you the exact measurement in this moment. And but, you know, I I you know, if it if it's even in question, I would, again, defer to the expert radiologists on both the plaintiffs' and the defense side who report that there is an enlarged spleen. So yes, I can't give you the exact measurements because I don't recall it off the top of my head. BY MR. VAUGHN: Q. And you're aware that his treating physicians at the time did not diagnose him with an enlarged spleen in 2016, correct? A. Yes, I'm aware of that. Q. And do you disagree with his treating physicians? A. Yes, I disagree with that. I disagree with that. It's it's it's unfortunately relatively common for for there to be	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	to it now, you can. A. Sure. That's okay. We can we can save it for later. Q. Okay. Have you ever diagnosed an enlarged spleen in practice? A. So I guess you mean it depends what you mean by, like, have I ever diagnosed a large spleen. I I definitely communicated a diagnosis of a large spleen to patients. But oftentimes you know, many aspects of medicine there are there are multiple, you know, physicians that have a role in in ascertaining a diagnosis. So so what I would typically do is I would order imaging for a patient, an ultrasound or a CT scan, whatever it might be. I'll look at the images myself, and then I will read the radiology report. And so if the radiologist reports an enlarged spleen, you know, and it's a radiologist that, you know, that that I that I'm accustomed to working with that I
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,	Page 138		Page 140
1	So it's it's a loop where I am	1	MS. ROSE: Object to the form.
2	ordering the study. I'm interpreting the read.	2	THE WITNESS: Yeah. As I stated
3	I'm, you know, having discussions with	3	previously, I I can't give you a
4	radiologists where relevant to to	4	specific measurement.
5	communicate what we think is is accurate to	5	MR. VAUGHN: All right. Now's a
6	the patient.	6	good time for a break, Nina.
7	So so yeah. It's usually not	7	MS. ROSE: Okay. Great.
8	just based on my own pure assessment. I always	8	THE VIDEOGRAPHER: Off the record
9	refer to the radiology reports to to assist	9	at 11:37 a.m.
10	with that, given that I'm not a diagnostic	10	(Whereupon, a break was taken.)
11	radiologist myself.	11	THE VIDEOGRAPHER: We are back on
12	Q. And so are you relying on the	12	the record at 11:53.
13	expert opinions either of the plaintiffs or	13	BY MR. VAUGHN:
14	defense in coming to the conclusion that	14	Q. All right. Doctor, so I want to
15	Mr. Roberts had an enlarged spleen in 2016?	15	stay here on Exhibit 5 where we have on
16	MS. ROSE: Object to the form.	16	U Penn's website exams and tests for cirrhosis.
17	THE WITNESS: I would say that	17	And we already talked about the spleen.
18	their their impressions, which I regard	18	As far as excessive breast tissue,
19	to be valid, given that they are	19	there was no evidence that Mr. Roberts had
20	diagnostic radiologists with expertise in	20	excessive breast tissue, correct?
21	this area, I had no reason to doubt that.	21	A. Not that I'm aware of.
22	And my process of looking at	22	Q. And prior his cancer diagnosis,
23	images, I I like to review the primary	23	there was no evidence he had a swollen abdomen
24	images myself just as a as a routine so	24	as a result of too much fluid, correct?
25	I I better understand and contextualize	25	A. Yes. I agree with that. There's
	Page 139		Page 141
1	what the radiologists are telling me.	1	no evidence of that prior to the cancer
2	For instance, if a radiologist said	2	diagnosis.
3	that there's no enlarged spleen and then I	3	Q. And prior to Mr. Roberts' cancer
4	take the time to do a measurement and I	4	diagnosis, there was no evidence of reddened
5	look up the upper limit of normal, and	5	palms, correct?
6	it's wildly discordant with the	6	A. Not that was documented on exam.
7	radiologists, I'd have a conversation with	7	Q. And prior to Mr. Roberts' cancer
8	them just to make sure that I'm not	8	diagnosis, there was no evidence of red
9	missing something.	9	spiderlike blood vessels on the skin, correct?
10	I I do this as a secondary check	10	A. Yeah. I think we already talked
11	for my own patients just to make sure	11	about that one in the previous one, but I
12	to minimize the probability of errors.	12	yeah. I did not see any specific documentation
13	But I think the fact that, you	13	of of that.
14	know, two expert diagnostic radiologists	14	Q. And for small testicles, was there
15	on the plaintiff and the defense side	15	any evidence that Mr. Roberts' testicles had
16	agree that there's splenomegaly, I I	16	shrunk prior to his cancer diagnosis?
17	put a lot of weight on that. I'll just	17	A. And again, I don't recall seeing
18	say that my own independent interpretation	18	that in the medical records specifically.
19	is consistent with that as well, though I	19	Q. Did you did you look for that?
20	give I give deference to them and put	20	A. Yeah. I mean, I I looked
21	more weight on their reports given their	21	through, you know, the document, exam findings.
22	expertise.	22	It's very uncommon for routine
23	BY MR. VAUGHN:	23	office visits to comment on testicular size
24	Q. And you can't tell us what size	24	unless the patient has a particular compliant
25	Mr. Roberts' spleen was in 2016, correct?	25	where they ask the physician to look at the
			= +

Page 142 1 testees. 2 So yeah. I don't recall that ever 3 being the case for him where someone looked at 4 him and documented his testees in their 5 physical exam. 6 Q. If someone suspected him of having Page 142 1 routinely look for is small testicles. 2 Q. And Mr. Roberts didn't have any 3 these prior to 2018 in his medical records 4 correct? 5 A. I don't recall seeing any of this 6 documented in his exam, but, you know,	
2 So yeah. I don't recall that ever 3 being the case for him where someone looked at 4 him and documented his testees in their 5 physical exam. 2 Q. And Mr. Roberts didn't have any 3 these prior to 2018 in his medical records 4 correct? 5 A. I don't recall seeing any of this	
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5 physical exam. 5 A. I don't recall seeing any of this	
6 (). It someone suspected him of having 16 documented in his examinate voil know	T) 1 1
7 cirrhosis, is that part of the exam that they 7 to emphasize these are things that someo	
8 would do? 8 an index of sufficient for cirrhosis would	
9 MS. ROSE: Object to the form. 9 would look for. So it's it's hard to know	
THE WITNESS: It is not part of the 10 if some of these might have been there or	not,
11 routine exam, no. 11 but they're not documented as such.	
12 Sorry. 12 Q. And then for tests on liver	
13 BY MR. VAUGHN: 13 function patient's complete blood cell cou	
Q. And so do you disagree with these 14 would that encompass the platelets that y	ou
15 as far as exams and tests on U Penn's website 15 were talking about?	
16 for cirrhosis? 16 A. Yes.	
17 A. No, I don't disagree with this. I 17 Q. And then prothrombin time, is the	
18 think these are potential exam findings that 18 the is that similar to the INR time you	were
19 may be found, but it'sthese things are not 19 discussing?	
20 required to make a diagnosis of cirrhosis. 20 A. Yes.	
So I think that's probably why 21 Q. Can you explain what those is	٠,
22 they they probably list these things as 22 there a difference between those two, or it	S IT
23 things your provider may do not that your 23 the same thing?	
24 provider has to do or absolutely will do. 24 MS. ROSE: Object to the form.	
25 I usually don't, you know, examine 25 THE WITNESS: They're they'	re
Page 143	Page 145
1 the testees unless the patient has a particular 1 very, very similar. They're you know	w,
2 complaint because it's not a diagnostic 2 the INR is sort of derived by the	
3 criterion for cirrhosis, and many patients find 3 prothrombin time, but I think in in	
4 it uncomfortable. So unless there's a specific 4 general practice, you'll see clinicians	
5 reason to look for it based on the patient 5 mainly refer to the INR. But when yo	
6 complaint, I won't routinely look at the 6 order something like the INR, it's it	S
7 testees, no. 7 usually listed as the prothrombin	
8 Q. Okay. And so this part where it 8 time/INR.	
9 says the provider will do a physical exam to 9 But, you know, in common just	
10 look for these things at U Penn, you don't 10 discussion among providers, we'll v	e'll
11 actually do those things, correct? 11 typically talk about what the	
12 A. I do most of these things. Like I 12 international normalized ratio sorry	
13 said, the testees the testees might be the 13 international normalized ratio.	
14 exception. I do look for just trying to 14 I'm trying to I'll try to slow	
15 read through this list. 15 down for for the stenographer. I	
16 Yeah. I mean, I will assess, you 16 apologize.	
17 know, spleen size. I will look for evidence of 17 We typically discuss things in	
18 ascites, which is swollen abdomen. I look at 18 terms of the INR, which is used more	
19 the palms in all my patients. I do look at for 19 commonly.	
20 the these telangiectasias, these spiderlike 20 BY MR. VAUGHN:	D.ID.
21 blood vessels in the skin. I look for I do 21 Q. And when you say prothrombin/	INK,
22 look for widened veins in the abdominal wall, 22 is that a PT/INR; is that how it is also	
23 and, of course, I look for yellow skin and 23 abbreviated?	
24 jaundice. 24 A. Yes. PT/INR is usually is	
25 As I said the only one that I don't 25 referring to prothrombin time/INR.	

Page 146 Page 148 1 Okay. And Mr. Roberts did not have 1 the albumin is another important lab. 2 an abnormal PT/INR prior to his cancer 2 Q. And then it mentions some other diagnosis, correct? 3 tests to check for, which includes a CT, MRI, endoscopy, and ultrasound, correct? A. I'd have to review them again in 4 4 5 detail, but I don't recall him having an A. Yes. I see that there on the page. 5 abnormal INR off the top of my head. 6 Okay. And feel free to look 7 On the CB- -- I apologize. 7 through the exhibit, but they don't mention --On the CBC is there anything you're 8 8 Penn Medical, where you work, they don't looking for there besides the platelet count to mention anything about a FIB-4 study to 9 10 be abnormal with cirrhosis? 10 diagnose cirrhosis, correct? 11 Sometimes, yeah. So I think 11 I don't see FIB-4 here. But again, 12 this is a -- like, a public-facing page that I 12 it's -- it's relevant to look at the hemoglobin 13 and the MCV, the mean corpuscular value. The expect patients will go to. 14 MCV is a -- it's a measure of the size of the If you try to start talking about 14 15 red blood cell. I do look at those as well. prediction modeling and FIB-4 scores, I think 15 16 that is probably needlessly confusing for the And I mean, I look at the white 16 17 blood cell count. I look at all aspects of the patient. That does not mean that it's -- it is 18 complete blood cell report, but some patients absolutely standard of care best practice for 19 with, you know, more advanced cirrhosis, you us to use a FIB-4 to help assist with making 20 may see their hemoglobin or their hematocrit these diagnoses and understanding the risk of 20 21 begin to downtrend because they may have 21 cirrhosis being present or not. 22 bleeding related to their cirrhosis. 22 Q. Let's go back to Exhibit 4. 23 So I -- I do look at that as well. 23 There's also a link here to nonfatty alcohol 24 That's more in the context typically of 24 liver disease. patients with more, you know, very advanced 25 MR. VAUGHN: And if you could drop Page 147 Page 149 1 cirrhosis. 1 that one next, Kathryn, that would be 2 Can you have a normal CBC and still 2 Exhibit 6. 3 have cirrhosis? 3 (Whereupon, Exhibit 6, Penn A. Yes. 4 4 Medicine Non-Alcoholic Fatty Liver 5 Can you have advanced cirrhosis and 5 Disease - Symptoms and Causes, was marked still have a normal CBC? 6 for identification.) 7 7 A. Yes. MS. AVILA: Okay. It's in there 8 MS. ROSE: Object to the form. 8 now. 9 BY MR. VAUGHN: 9 BY MR. VAUGHN: 10 Q. The liver function test that it's 10 Q. Doctor, what is nonalcoholic fatty 11 talking about here, is that the AST and ALT you 11 liver disease? 12 were discussing earlier? 12 So nonalcoholic fatty liver 13 A. The liver function tests typically 13 disease, I'll -- I'll first say that this is an 14 encompasses a number of different labs. It out- -- outdated term. So it's -- it's some 15 includes the AST, the ALT, the total bilirubin, 15 clear indication that this website -- I don't 16 the theophylline phosphatase, the albumin, and know how frequently it's updated, but the 16 17 usually the total protein is also reported with current term is MASLD, M-A-S-L-D, which is 17 18 that. It's a panel, yeah. 18 metabolic dysfunction-associated steatotic 19 Q. And then the blood albumin levels, 19 liver disease. 20 you were talking about that as well for 20 So I may refer to, you know, the 21 advanced cirrhosis, right? same entity as MASLD or NAFLD, where, you know, 21 A. Yes. The blood al- -- yeah. It's 22 depending on convenience or referring to 23 actually -- it's usually encompassed in the 23 other -- other references from Dr. Siddiqui or 24 liver function tests that you send. It 24 elsewhere. 25 typically batches those all together. But yes, 25 But what I'm referring to NAFLD or

1	Page 150	1	Page 152
$\frac{1}{2}$	MASLD is the presence of fat in the liver that	1	unless it progresses, you know, to a very
2	is not related to alcohol but is typically	2	advanced cirrhosis.
3	related to individuals who have excess body	3	Q. And then this notes a more severe
4	weight who are overweight or obese. It's very	4	form of NAFLD is NASH.
5	commonly associated with other metabolic	5	What what is NASH, and what is
6	conditions like high cholesterol, high blood	6	the difference between NASH and NAFLD?
7	pressure, diabetes. Things like this are	7	A. So here's another instance where
8	oftentimes they're very co-associated. They	8	I'll introduce maybe two terms because there's
9	oftentimes present together.	9	also an updated nomenclature for NASH, which is
10	But it's a spectrum of liver	10	now MASH, M-A-S-H. Which, these entities,
11	disease where when fat is present in the liver	11	again, they refer to the same principle.
12	in that context, the the liver doesn't like	12	But NASH, the acronym is
13	that. The fat induces inflammation.	13	nonalcoholic steatohepatitis. And MASH, with
14	As I explained previously,	14	an M, is metabolic dysfunction-associated
15	inflammation over time leads to scar tissue.	15	steatohepatitis. It's all very confusing
16	When more scar tissue accumulates, eventually	16	unfortunately in the world the hepatology.
17	it can become cirrhosis.	17	But essentially, what this is, it
18	But that's the spectrum generally	18	means that in addition to there being fat in
19	of what NAFLD and MASLD is.	19	the liver related to, you know, being
20	Q. And do you agree with this part	20	overweight, et cetera, there is also
21	where it says, "NAFLD" "For many people,	21	inflammation.
22	NAFLD causes no symptoms or problems."	22	Some patients will have NAFLD.
23	Do you agree with that?	23	They'll have fat in the liver, but it's,
24	A. Yeah. I think I would agree with	24	quote/unquote, "bland" where there's there's
25	that. I mean, you know, referring specifically	25	fat there, but there's no inflammation.
	Page 151		Page 153
1	to the NAFLD, many people won't even know they	1	NASH and MASH imply that the fat is
1 2	to the NAFLD, many people won't even know they have it because, you know, fat in the liver by	1 2	NASH and MASH imply that the fat is causing inflammation, and, thus, you know,
l _	to the NAFLD, many people won't even know they have it because, you know, fat in the liver by itself doesn't cause symptoms. I mean, it's		NASH and MASH imply that the fat is causing inflammation, and, thus, you know, putting a patient at risk of of accumulating
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	5 44		n
1	Page 154 it's hard to disassociate is it fatigue	1	Page 156 There's compensated and decompensated.
2	related to the fat, or is it related to	$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	I was just trying to the refer to
3	the other metabolic conditions that many	3	the fact that decompensated cirrhosis is more
4	of these patients invariably have, like,	4	advanced progression beyond compensated
5	you know, diabetes, for instance.	5	cirrhosis.
6	BY MR. VAUGHN:	6	Q. And you agree that cirrhosis is a
7	Q. And for the progression of NAFLD to	7	progressionary disease, right?
8	NASH, once you're at NASH symptoms include	8	A. Yeah. I do agree that I mean,
9	weakness, loss of appetite, nausea, yellow skin	9	the diagnosis of cirrhosis is very much binary,
10	and eyes which is jaundice, itching, fluid	10	like, we either think it's there or not. But
11	buildup and swelling in the legs and abdomen,	11	there is a spectrum within cirrhosis where
12	mental confusion, and GI bleeding, correct?	12	there can been additional progression of scar
13	A. So those are not it might be.	13	where things ultimately evolve from compensated
14	Those are not specific symptoms to NASH. Many	14	to decompensated cirrhosis.
15	of those are things you expect to see in	15	Q. So I want to make sure I'm clear on
16	patients who have NASH that have progressed to	16	this.
17	cirrhosis.	17	There's fibrosis. There's advanced
18	I think they qualify that there.	18	fibrosis, and then there's cirrhosis, correct?
19	They say, "In people with NASH who have liver	19	A. Yeah.
20	damage (cirrhosis)."	20	MS. ROSE: Object to the form. I'm
21	You know, many many of these	21	sorry. I didn't mean to interrupt you,
22	symptoms are related to cirrhosis, and some of	22	Doctor. I want to get my objection in.
23	them are more specific to even more advanced	23	THE WITNESS: I will give you more
24	cirrhosis, not necessarily, you know, NASH	24	time. I apologize.
25	itself always.	25	So just to be clear, fibrosis,
	Page 155		Page 157
1	Q. And did Mr. Roberts have any of	1	again, is just the medical term that means
2	Q. And did Mr. Roberts have any of these symptoms prior to his cancer diagnosis in	2	again, is just the medical term that means scar. So it's not really specific in
2 3	Q. And did Mr. Roberts have any of these symptoms prior to his cancer diagnosis in 2018?	2 3	again, is just the medical term that means scar. So it's not really specific in terms of any implication of how much scar.
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	Page 158		Page 160
1	decompensated cirrhosis advanced cirrhosis?	1	a description of the appearance of the liver
2	A. Just to I'll I'll just be	2	under a microscope.
3	very precise about that.	3	So by a very technical definition,
4	I mean, so decompensated cirrhosis	4	NASH or MASH, you can really only technically
5	is defined based on the manifestation of of	5	see it if you're looking at the biopsy.
6	cardinal symptoms of of advanced liver	6	That being said, these days we do
7	disease or advanced cirrhosis. And ascites,	7	not commonly perform liver biopsy. We do in
8	confusion related to the liver, which is called	8	some scenarios, but far less than we used to.
9	hepatic encephalopathy in a particular type	9	We are able to generally infer if a patient has
10	of of GI bleeding from varicose veins in the	10	NASH or MASH without subjecting them to a liver
11	GI tract.	11	biopsy.
12	If any of those are present, it's	12	So yeah. I think it's it's
13	referred to as decompensated cirrhosis. That's	13	technically true; but in modern practice, we
14	the medical terminology.	14	we don't usually routinely put patients with
15	If I say "advanced cirrhosis," I'm	15	NAFLD and concern for possible NASH through a
16	doing that just for the benefit of, I suppose,	16	biopsy. We use evidence from their blood work,
17	just being able to communicate the principle	17	for instance, and their fibrosis or their FIB-4
18	more easily without having to rely exclusively	18	score to infer that there's MASH or NASH
19	on the medical terminology, though, if you	19	occurring that if we did do a biopsy, we would
20	prefer, I can just refer to that as	20	expect to see it.
21	decompensated cirrhosis.	21	Q. And Penn Med's website doesn't
22	Q. And I	22	mention anything about FIB-4 then when
23	A but that's what I mean when I	23	diagnosing NASH, does it?
24	Q. I appreciate that. That's a	24	A. It does not. But like I said
25	helpful clarification.	25	previously, this appears to be a patient-facing
	Page 159		Page 161
1	So for a layperson or to the jury,	1	website. I don't think this website is

2 using the words like "advanced cirrhosis" could be easier to get that message across than just saying "decompensated cirrhosis," correct? 5 MS. ROSE: Object to the form. 6 THE WITNESS: Yeah. I -- I think 7 I -- I can certainly explain decompensated 8 cirrhosis very specifically, but all I'm 9 trying to communicate with the word 10 "advanced" is that there has been 11 progression from a compensated state to a 12 decompensated state. 13 BY MR. VAUGHN: 14 All right. Do you see down here on 15 U Penn's website, "A liver biopsy is needed to 16 confirm a diagnosis of NASH, the more severe 17 form of NAFLD"? 18 Do you agree with that? 19 A. I do agree with that from a 20 technical -- it's a very technical standpoint, and the reason why I say that is if you're 22 being a medical purist, the only way to state that someone has NASH or MASH is to get a liver

24 biopsy because it's a -- it's technically a

25 pathological diagnosis. You -- it's a -- it's

2 comprehensive in describing all aspects of

3 liver disease; but, you know, I can represent

4 to you that, you know, FIB-4 is -- it's, you

5 know, it's codified in, you know, practice

guidelines for hepatology and in particular,

actually, in surveillance for patients with

MASLD or NAFLD, and which terminology you want

to use. You know, FIB-4 is used routinely.

And there was no liver biopsy

11 conducted on Mr. Roberts prior to his cancer

12 diagnosis, correct?

10

13

A. That is correct. I do recall maybe

14 it was Dr. Ives, I believe, one of his -- his

gastroenterologists, at some point early in the

16 records, he had offered him a liver biopsy. I

believe he had suspected that -- you know, he

18 had -- he had demonstrated on an ultrasound

that there was fat in the liver and in the --

in the setting of abnormal AST and ALT and

offered Mr. Roberts liver biopsy. And

22 Mr. Roberts, I think, did not want to pursue

23 that.

24 Q. And in a liver biopsy, if someone

25 does have NASH as opposed to NAFLD, what --

41 (Pages 158 - 161)

	2.40		
1	Page 162 what are you looking for?	1	Page 164 Q. So am I right in saying that there
2	MS. ROSE: Object to the form.	2	does not need to be cirrhosis on the biopsy for
	THE WITNESS: So I apologize.	3	a diagnosis of NASH?
3		4	
5	Can you repeat the question. BY MR. VAUGHN:		A. Oh, yes, that's correct. Yeah.
6		5	Many patients might have NASH, but they don't have cirrhosis.
	Q. Yeah. Where where it says, "A liver biopsy is needed to confirm the diagnosis	7	
7	· ·		So you could have somebody that has
8	of NASH, the more severe form of NAFLD," what	8 9	NASH but only Stage 1 fibrosis. You could have someone that has NASH, but they have Stage 3
9	is going to be in that liver biopsy to indicate that it is NASH as opposed to NAFLD?	10	•
10			fibrosis. Then you can have someone that has
11	A. I see. Right.	11	NASH, and they have overt cirrhosis F4
12	So on a liver biopsy, what you	12	cirrhosis.
13	expect to see in someone that has MASLD or	13	So you can make you can
14	NAFLD is you expect to see an increase of fat	14	encounter a biopsy across the whole spectrum.
15	content inside liver cells. That's that's	15	Q. Okay. So the biopsy for the
16	what the medical term steatosis means.	16	diagnosis of NASH is primarily looking for the
17	Steatosis just means fat. You expect to see an	17	addition of inflammation in the liver to
18	abnormal abnormal amount of fat in liver	18	distinguish it from NAFLD?
19	cells.	19	A. Yes.
20	The MASH and NASH part of it means	20	Q. Okay.
21	that you additionally expect to see markers of	21	A. Fat plus inflammation is is MASH
22	inflammation. You expect to see inflammatory	22	or NASH.
23	cells, so a certain types of white blood cells.	23	Q. Okay. And we do not have a biopsy
24	There are also other, you know, particular, you	24	showing inflammation of Mr. Roberts' liver
25	know, kind of pathology-based findings, like	25	prior to 2018, correct?
1	Page 163	1	Page 165 A. That's
$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	ballooning, degeneration, and other things that the pathologists may comment on that are also	2	MS. ROSE: Object to the form.
$\frac{2}{3}$	consistent with MASH or NASH.	3	THE WITNESS: correct.
4	But broadly speaking, you're	4	
5	looking for evidence of inflammation plus fat	5	Sorry. MS. ROSE: That's okay.
6	not just fat alone.	6	THE WITNESS: That's correct. But
7	Q. For the diagnosis of NASH, are you	7	as I stated previously, really in this era
8	also looking for the presence of cirrhosis or	8	of practice, we don't routinely perform
9		9	liver biopsies to demonstrate NASH. We
10	just the presence of inflammation? A. That's a very good question.	10	infer it based on a laboratory evaluation,
11		11	and it's only in scenarios where there's
12	On the biopsy the pathologists will always perform something called a trichrome	12	· · · · · · · · · · · · · · · · · · ·
13	stage trichrome stain, which is a special	13	really diagnostic uncertainty where we might discuss biopsy as being an important
14	way of looking at the amount of scar tissue in	14	diagnostic step for a patient.
15	the liver.	15	BY MR. VAUGHN:
16	So yeah. It's very routine where	16	
17	in addition to trying to assess what is the	17	Q. All right. And it lists treatments.
18	chronic liver disease process that is present	18	And for treatment for NAFLD, it
19	on a biopsy, they will also report the stage of	19	mostly just talks about managing risk factors,
20	fibrosis.	20	correct?
21	So that that's where this	21	A. So let me scroll through this.
22	terminology for F0 to F4 fibrosis comes from.	22	Q. Oh, you're fine. Take your time.
23	So the pathologists will usually try to make a	23	A. Yeah. Yeah.
24	determination of how much fibrosis or scar	24	It does primarily focus on
	tissue is there on a biopsy.	25	risk-factor management. Although, I will say
	about to their on a dropoj.		11011 1attor management. Timough, I will buy

Γ				
		Page 166	1	Page 168
		1 5	1	to market?
	2	like it's outdated because they're using the	2	A. It came to market after Mr. Roberts
	3	old nomenclature for NAFLD.	3	had passed away. I can't recall the exact
	4	But, you know, in the interval	4	date. I believe it was in you know, off the
	5	this is not necessarily so relevant to this	5	top of my head, it was probably in 2023.
	6	case but there is now a specific, you know,	6	Q. And prior to that, for NAFLD
	7	medical treatment for patients with with	7	specifically, the treatment was to manage risk
	8	MASH that's not listed here.	8	factors?
	9	But setting that aside, okay. So	9	A. Yes, I'd say so. Yeah.
		it's a relatively recent development. This is	10	Q. Okay.
	11	otherwise generally accurate. I mean, the main	11	A. Again, minimize taking steps to
	12	management for MASLD/MASH is lifestyle changes		minimize alternative causes of liver disease.
	13	and working on weight loss in particular.	13	Q. And Mr. Roberts was overweight,
	14	So weight loss is the is the	14	correct?
	15	primary recommendation. And so things that are	15	A. Well, he was he had Class 2
	16	in service of trying to promote weight loss are	16	obesity. So overweight is a specific medical
	17	the primary recommendation because the only way	17	term that refers to a BMI between 25 and 30.
	18	to get the fat out of the liver, essentially,	18	And then above 30 is obesity. And then there's
	19	is to to lose weight, get fat out of the	19	different classes of obesity. There's Class 1,
	20	body; and then fat will start to leave the	20	which is 30 to 35. There's Class 2, which 35
	21	liver, and the inflammatory process will start.	21	to 40, and there's Class 3, which is over 40.
	22	And then, of course, other best	22	So just to be precise, he was
	23	practices of management are to not do things	23	fairly consistently in the Class 2 obesity
	24	that would additionally injure the liver beyond	24	range with a BMI between 35 and 40.
	25	NASH or MASH.	25	Q. So he was overweight or fat, and
İ		Page 167		Page 169
	1	So that's that's where these	1	that then leads to fat in the liver?
	2	recommendations of, you know, related to	2	MS. ROSE: Object to the form.
	3	alcohol use and being vaccinated on hepa	3	THE WITNESS: And again, he had
	4	against Hepatitis A and Hepatitis B, these are	4	he had Class 2 obesity. So it's
	5	measures to further protect the liver from	5	it's it's multiple degrees above just
	6	injury.	6	being overweight.
	7	Q. What treatment options are there	7	But but yes. I mean, folks who
	8	now for NAFLD that you mentioned?	8	are, you know, are obese and some who are
	9	A. There's a medication that was FDA	9	just overweight can have excess fat in
	10	approved that's called resmetirom. I'm happy	10	their body, and some of that fat goes into
	11	to spell that if you need me to. Resmetirom,	11	the liver and causes this pathology that
	12	R-E-S-M-E-T-I-R-O-M. The brand name is	12	we've been talking about.
	13	Rezdiffra, and it's a medication that's used	13	BY MR. VAUGHN:
	14	for a subset of patients with NASH who have	14	Q. And Mr. Roberts weighed about
	15	Stage 2 or 3 fibrosis.	15	what was it about 250 pounds?
	16	Q. Oh, so is it just to treat NASH not	16	A. I don't recall his exact weight in
	17	NAFLD?	17	pounds, but I recall his BMI range. BMI is
	18	A. Yes, it's used to treat NASH.	18	oftentimes a little more relevant because
	19	Q. Okay.	19	some you know, the height of the patient is
	20	A. Well, I assume NAFLD encompasses	20	very, you know, important to know with respect
	21	NASH. It's like an umbrella term. But but	21	to interpreting the weight.
	22	yes, it's specifically indicated with patients	22	So his BMI range was very often 37,
	23	that have NASH. You wouldn't use it in someone	23	38. I think at times it may have been even
	24	that had fat in the liver but no inflammation.	24	around 39, but he was very consistently in the
- 1		In the man and man		

25 range of Class 2 obesity.

Q. And when did that medication come

25

	D 170		D 173
1	Page 170 Q. Okay. And he didn't lose weight	1	Page 172 context around that.
2	prior to being diagnosed with cancer, did he?	$\frac{1}{2}$	And the quote from the report was
3	MS. ROSE: Object to the form.	3	he was diagnosed with proximal atrial
4	THE WITNESS: I mean, he he's	_	fibrillation after, quote, "significal [sic]
5	had you know, he had minor fluctuations	5	significant alcohol intake that occurred at his
6	in his body mass index. But it's fairly,	_	hunting camp.
7	you know, consistently documented from a	7	So it's not it's not totally
8	lot of his providers that he's been unable	8	accurate to say that he never had any
9	to lose weight despite recommendations to	9	documentation of alcohol use. That's one that
10		^	
11	lose weight.	l .	I recall seeing, and I and I documented that
12	So, you know, he he never had	11 12	in my medical record review.
13	really a strong, sustained trend of being		So at least on that occasion, you
l	able to lose weight it seems like through	13	know, he reported significant alcohol use to
14	his own lifestyle changes.	14	the point where he was diagnosed with an
15	BY MR. VAUGHN:	15	arrythmia. BY MR. VAUGHN:
16	Q. And did you see in his medical	16	
l	records that he as was attempting most	17	Q. And after someone is diagnosed with
18	lifestyle changes, such as eating a healthier diet?	18	NAFLD or NASH, they should quit drinking
19		19	alcohol, correct, or limit alcohol intake?
20	A. I don't know to what extent he was,	20	A. Yeah. I
21	you know, actively operationalizing those	21	MS. ROSE: Object to the form.
22	recommendations. I know those recommendations	22	THE WITNESS: Sorry.
23	were made to him, but, you know, yeah. I don't	23	Yes. I'd say that there's a little
24	recall, like, much granular detail that the	24	bit of a nuance to that. If somebody has
25	providers were providing in their notes about	25	MASLD or NAFLD and they have absolutely no
	Page 171		Page 173
1		1 1	
١ ـ	what specific dietary change he was making or	1	fibrosis, in my view they don't have to
2	what changes to his exercise routine he was	2	strictly abstain from all alcohol.
2 3	what changes to his exercise routine he was he was making.	2 3	strictly abstain from all alcohol. The patient's where it's an
2 3 4	what changes to his exercise routine he was he was making. So I wouldn't be able to give a	2 3 4	strictly abstain from all alcohol. The patient's where it's an absolute recommendation are those who have
2 3 4 5	what changes to his exercise routine he was he was making. So I wouldn't be able to give a clear assessment of that based on the records	2 3 4 5	strictly abstain from all alcohol. The patient's where it's an absolute recommendation are those who have cirrhosis. If you have cirrhosis, it's a
2 3 4 5 6	what changes to his exercise routine he was he was making. So I wouldn't be able to give a clear assessment of that based on the records that I recall seeing.	2 3 4 5 6	strictly abstain from all alcohol. The patient's where it's an absolute recommendation are those who have cirrhosis. If you have cirrhosis, it's a strict recommendation from physicians that
2 3 4 5 6 7	what changes to his exercise routine he was he was making. So I wouldn't be able to give a clear assessment of that based on the records that I recall seeing. Q. And did you see that he was not	2 3 4 5 6 7	strictly abstain from all alcohol. The patient's where it's an absolute recommendation are those who have cirrhosis. If you have cirrhosis, it's a strict recommendation from physicians that you should not drink alcohol at all.
2 3 4 5 6 7 8	what changes to his exercise routine he was he was making. So I wouldn't be able to give a clear assessment of that based on the records that I recall seeing. Q. And did you see that he was not drinking alcohol?	2 3 4 5 6 7 8	strictly abstain from all alcohol. The patient's where it's an absolute recommendation are those who have cirrhosis. If you have cirrhosis, it's a strict recommendation from physicians that you should not drink alcohol at all. Sorry. Excuse me.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	what changes to his exercise routine he was he was making. So I wouldn't be able to give a clear assessment of that based on the records that I recall seeing. Q. And did you see that he was not drinking alcohol? MS. ROSE: Object to the form. THE WITNESS: So from the records, many records say that there's no significant alcohol use; but that was not uniformly the case. I recall specifically so I'm just trying to find it really quickly. BY MR. VAUGHN: Q. Uh-huh. A. Yeah. So October 26th of 2012 Q. Uh-huh. A he was with Dr. Bullard in pulmonology clinic for his obstructive sleep apnea. And in the in that documentation	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	strictly abstain from all alcohol. The patient's where it's an absolute recommendation are those who have cirrhosis. If you have cirrhosis, it's a strict recommendation from physicians that you should not drink alcohol at all. Sorry. Excuse me. But yes. In patients that I'm worried have MASH or NASH and are at a high likelihood of progressing to cirrhosis, I will counsel them to ideally avoid alcohol entirely; and, you know, in the very least, they need to to limit their alcohol intake to upper limits of of what's generally thought to be safe for males and females. BY MR. VAUGHN: Q. And so you found the record in 2012 of him drinking on a hunting trip. Do you have any evidence of him drinking after that time point?
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	what changes to his exercise routine he was — he was making. So I wouldn't be able to give a clear assessment of that based on the records that I recall seeing. Q. And did you see that he was not drinking alcohol? MS. ROSE: Object to the form. THE WITNESS: So from the records, many records say that there's no significant alcohol use; but that was not uniformly the case. I recall specifically — so I'm just trying to find it really quickly. BY MR. VAUGHN: Q. Uh-huh. A. Yeah. So October 26th of 2012 — Q. Uh-huh. A. — he was with Dr. Bullard in pulmonology clinic for his obstructive sleep apnea. And in the — in that documentation Mr. Roberts had been diagnosed with atrial	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	strictly abstain from all alcohol. The patient's where it's an absolute recommendation are those who have cirrhosis. If you have cirrhosis, it's a strict recommendation from physicians that you should not drink alcohol at all. Sorry. Excuse me. But yes. In patients that I'm worried have MASH or NASH and are at a high likelihood of progressing to cirrhosis, I will counsel them to ideally avoid alcohol entirely; and, you know, in the very least, they need to to limit their alcohol intake to upper limits of of what's generally thought to be safe for males and females. BY MR. VAUGHN: Q. And so you found the record in 2012 of him drinking on a hunting trip. Do you have any evidence of him drinking after that time point? A. No. I don't I don't recall

Page 174 Page 176 1 thinking that he was drinking a significant 1 non reactive; but the Hepatitis B surface 2 amount or nothing that was really reported by 2 antibody was detected at a level of greater 3 him, as best as I can tell. than 11.5. Q. And did you see in the records of 4 So my interpretation of that is he 4 5 him being physically active, such as going on 5 was never infected or exposed to Hepatitis B hunting trips throughout 2012 through his virus, which is why the surface antigen and the diagnosis of cancer? core antibody were negative; but he had 7 immunity. He was -- he was likely vaccinated 8 A. I recall that instance of the 8 9 hunting trip, and there might have been a against Hepatitis B because he had the antibody 9 10 fishing trip mentioned somewhere else. I may 10 detected. 11 be misremembering that, but I don't know. You 11 O. And was he on medication to lower 12 can -- it's kind of debatable how active a 12 his cholesterol and triglyceride levels? 13 fishing trip or hunting trip are. And, you 13 MS. ROSE: Object to the form. 14 know, I don't know what regularity Mr. Roberts 14 THE WITNESS: Yeah. I -- again, I 15 may have engaged in -- in these types of 15 don't believe for much of his history. I 16 activities. don't recall him being treated with a 16 17 So it's -- it's tough from the 17 statin, which is what's typically used for 18 record, in my view, to get a really strong 18 controlling, you know, high LDL levels. 19 sense of how much physical activity he was 19 But he did carry a diagnosis of 20 engaged with in the course of his kind of 20 hyperlipidemia that was reported in 21 routine care during the course of his medical 21 November of 2006, but I don't recall him 22 record history. 22 really being on a lipid-lowering agent 23 And he was taking medications to 23 certainly later in his medical record 24 24 manage his blood pressure and diabetes, history. I don't recall that being really 25 correct? 25 clearly demonstrated even in his early Page 175 Page 177 1 A. Yes. 1 medical history. 2 And he did not have Hep A or Hep B, 2 BY MR. VAUGHN: Q. 3 correct? 3 Q. Did he have elevated cholesterol 4 and trigly- -- triglycerides? 4 A. Correct. Q. A. Yes. He definitely had an elevated 5 Do you know if he was vaccinated 5 against such diseases? LDL and triglycerides. I wrote down some of 7 A. Sorry. Let me look at my report. those. So for instance, September 20th, 2005, 8 Yes, I do. I just wanted to pull 8 he had a triglyceride value of 390, a 9 it up because I wrote these labs down. I just 9 cholesterol value of 230. 10 wanted to make sure I present it to you 10 And on November 14th, 2006, he had 11 accurately. 11 an LDL that was very clearly elevated at 153. 12 So on July 18th of 2018, a lot of 12 So that's usually -- LDL is what is 13 most commonly used, you know, from my 13 that relevant laboratory data had been sent understanding, from primary physicians and 14 off, I believe, by Dr. Hooks his -- his 15 gastroenterologist. cardiologists to make decisions primarily about 16 And so he had some Hepatitis A 16 the need for medications like statins to lower 17 and B related serology data. So his LDL, which is oftentimes referred to be the. 18 Hepatitis A antibody was nonreactive. They quote/unquote, "bad cholesterol." 18

45 (Pages 174 - 177)

So an LDL of 153 is -- is elevated.

I -- I just can't recall if he was

or not. He might have been on -- if he was on

Q. Is Crestor a statin?

A. Crestor is a statin. Yeah.

Was he on Crestor?

25 Crestor, then that is a statin at that time

19

20

21

22

23

24

24

19 don't report if that's an IgG or IgM antibody,

21 when a lab reports it that way, it's the IgG

20 which would be relevant. But most of the time

22 antibody that is nonreactive, which would imply

However, Hepatitis B he had surface

23 that he was not vaccinated against Hepatitis A.

25 antigen nonreactive, Hepatitis B core antibody

	Dags 170		Page 190
1	Page 178 point. I just don't recall seeing that	1	Page 180 medications as being a Band-Aid on top of
2	reliably later in his record.	2	the root cause to try to mitigate the
3	Q. So as far as managing his risk	3	injury related diabetes, high blood
4	factors for NAFLD, he was basically doing	4	pressure, high cholesterol. But the root
5	everything except for actually losing the	5	cause is the weight, and that was not
6	weight, correct?	6	addressed successfully really at any point
7	MS. ROSE: Object to the form.	7	in in his history.
8	THE WITNESS: Yeah. I think in	8	BY MR. VAUGHN:
9	terms of managing the comorbid conditions	9	Q. Do you think Mr. Roberts got liver
10	associated with MASLD and NAFLD, which are	10	cancer because he was overweight?
11	things like hyperlipidemia, hypertension,	11	A. I think that again, he was
12	diabetes, if you're representing to me		Class 2 obesity, not just overweight.
13	that he was on Crestor and that it is just	13	I do think that obesity was part of
14	slipping my memory, then I'll take you at	14	the picture. I don't think it's the entire
15	your word that he may have been on	15	explanation. I think it's related to why he
16	Crestor. That would be appropriate	16	developed cirrhosis, and I think it also has
17	management for for hyperlipidemia.	17	some independent contribution to the increased
18	I know he was on medications for	18	risk of liver cancer.
19	hypertension, of course, different ones	19	So it's it's not an isolated
20	over time. I think around the time of his	20	thing. I don't think it's just the Class 2
21	hyperlipidemia, he was on Celiprolol and	21	obesity. It's really the process the main
22	hydrochlorothiazide. And later was was	22	thing in my view is the process of MASLD and
23	switched to different agents.	23	MASH progressing to cirrhosis. Because once
24	And then later in his history with	24	there's cirrhosis that that is, you know,
25	diabetes, he was on Metformin and another	25	the best established risk factor for developing
23	·		
1	Page 179 medication, a secondary medication for	1	Page 181 hepatocellular carcinoma.
2	diabetes.	2	So insofar as, you know, it's
3	So yes, I would agree that	3	related to causing cirrhosis and has some
4	generally speaking, he was receiving	4	elevated independent risk beyond that, so it's
5	pharmacologic therapy for those comorbid	5	part of the picture; but it's not the entire
6	conditions. However, as I said	6	explanation.
7	previously, the most important central	7	Q. If Mr. Roberts was not obese, do
8	aspect of managing MASLD and NAFLD and the	8	you believe that he would have developed cancer
9	only thing that's effective is weight loss	9	when he did?
10	and demon demonstrability to achieve	10	MS. ROSE: Object to the form.
11	sustained longitudinal weight loss. And	11	THE WITNESS: So I mean, you're
12	without that, the NAFLD and the NASH	12	giving me a hypothetical. So so, you
13	the MASLD and the MASH, they won't go	13	know, I'll answer that, you know, with
14	away; and they'll continue to cause liver	14	that in mind; and I'll would you like
15	injury and eventually cirrhosis.	15	me to assume that everything else is in
16	So the comorbid conditions that	16	the same?
17	that come along with this is a package	17	So he
18	oftentimes because weight is the	18	BY MR. VAUGHN:
19	underlying thing that is the central risk	19	Q. Correct.
	factor for all those conditions is the	20	A is not obese?
20		21	Okay. So if you take out. It's a
	root cause. And I don't think the root	2 I	
20		22	
20 21	cause of all of those things was being		little bit tough to tease out entirely because
20 21 22		22	
20 21 22 23	cause of all of those things was being managed. I mean, he didn't lose weight,	22 23	little bit tough to tease out entirely because the obesity is interrelated to things.

Page 182 Page 184 1 likely to have MASLD. He'd be less likely to 1 think it's maybe -- I'm not sure if they're 2 referring specifically to NAFLD-related health 2 have NASH. He'd be less likely to have 3 diabetes, high blood pressure, hyperlipidemia, problems, in which case maybe it's a fair 4 coronary artery disease. 4 statement. 5 5 So in that hypothetical, he would My position generally is, as I've 6 be a much, much healthier patient. So it's --6 stated, many patients with NAFLD, they tend to 7 it's hard to perfectly project what would have 7 be overweight. They tend to be obese, and that 8 happened. But if he was a normal weight, 8 puts them at a higher risk of having other 9 there's a very good chance that he would have problems like diabetes, high blood pressure, 10 never developed cirrhosis; and therefore, you 10 high cholesterol. It's a very, very 11 know, there's a very good chance that he would well-demonstrated association, you know, 11 12 have never developed hepatocellular carcinoma. including features of the metabolic syndrome. 12 13 Yes. 13 These are co-associated. 14 And -- and so to be clear, it's 14 So perhaps what they're referring 15 to there is just NAFLD-related health problems, 15 because he was overweight, he developed which I think is fair. But I think my -- my --16 cirrhosis, in your opinion; and then the 17 cirrhosis led to his cancer? my perspective is I probably would have written that a bit of a different way because patients 18 MS. ROSE: Object to the form. 19 THE WITNESS: That's not what I'm with NAFLD are more likely to have these other 20 20 important comorbidities. saying. 21 21 Do you agree that many people with I said that there are multiple 22 important risk factors to consider in this 22 NAFLD do not go on to develop NASH? 23 case. Cirrhosis is one of them. And 23 Yeah. I would agree with that. 24 there are multiple factors that are 24 Many patients, you know, have bland fat in the 25 related to his developing cirrhosis, 25 liver and -- and don't develop NASH. There's a Page 183 Page 185 1 including Class 2 obesity as well as MASLD subset of patients that do. 1 2 and MASH and -- and diabetes for -- for 2 Q. Can you give me an approximate percent of people with NAFLD that go on to 3 that factor. 3 4 4 develop NASH? But, you know, as I state in my 5 expert report, it's not just the 5 Yeah. I don't want to give you the 6 cirrhosis. You know, diabetes, obesity, wrong figure. I mean, I can give you ballpark estimates of some of these things. But, you 7 MASLD, and MASH, those are also 7 know, yeah. I'd have to really kind of look at 8 independent risk factors for 8 9 hepatocellular carcinoma. 9 the literature again to give you really precise 10 And just to make that really 10 estimates. 11 crystal clear, a very good demonstration 11 But roughly a third of individuals of that is the fact that many patients 12 12 in the United States have NAFLD. We are, with MASH develop hepatocellular carcinoma 13 unfortunately, a very generally obese country 13 14 with poor lifestyle habits. So NAFLD is very, in the absence of cirrhosis. 14 15 So cirrhosis is not a prerequisite 15 very common. One in three people have it. 16 state. It's -- it is a very, very high 16 You know, NASH develops as a subset. I don't know exactly know, you know, 17 risk state for liver cancer, but the other 17 what proportion may have NASH. But -- but 18 factors matter too, independently. 19 BY MR. VAUGHN: 19 broadly speaking, there's roughly -- there -- I 20 Q. On the outlook or prognosis for 20 think of it in terms of kind of -- if I see a 21 NAFLD on Penn Med's website it says, "Many patient with NAFLD, I can give you estimates 22 people with NAFLD have no health problems and 22 for timeframes of progression to other phases 23 do not go on to develop NASH." 23 of -- of -- of fibrosis that informs sort of Do you agree with that statement? 24 the risks of NASH and then cirrhosis. 24 25 Not really, honestly. It's a -- I 25 If you see a patient with -- with

Page 186 Page 188 1 MASLD or NAFLD, they typically will -- you 1 that some patients might get a little bit of 2 know, there's a risk of progressing to the next 2 improvement if -- when they're appropriately 3 stage of fibrosis in about five to seven years. 3 managed. You can some reduction in the degree So through that lens, you can sort of scar, but typically not total resolution. 4 5 of get estimates, you know, broadly of how many 5 To give you just an example of patients will progress these stages to have where that literature -- excuse me -- comes significant MASH and then cirrhosis, but I from or maybe just explain this in a very 7 don't have a really precise number of, like, 8 lay -- lay -- lay terminology really quickly. what proportion of patients with NAFLD have 9 Scar in the body is very similar to 10 NASH. I don't know if we necessarily have 10 scar that you can see on the outside. So like, 11 really accurate estimates of that honestly. 11 if you're a kid and you fall and you cut your Q. Would you agree that most people 12 12 knee and you get a scar there, you usually have who are obese have NAFLD? 13 that scar there your whole life. It's A. That's probably the case that most 14 generally the same principle on the inside. So 14 15 people who are obese likely have NAFLD or 15 if you have something that causes scar inside 16 MASLD, yes. I don't know exact -- the exact 16 an organ, that tends to also stick around your whole life. 17 proportions, but I would expect that most 17 18 individuals do have fat in the liver if they're 18 But -- but we know from some 19 obese. 19 studies -- and this is primarily from the 20 bariatric surgery literature -- where some Q. Okay. We were talking about how 21 losing weight can help treat or reverse NAFLD. patients that have NASH or MASH and they've 22 Does that mean that the fatty undergone a biopsy in these studies to 22 23 deposits within the liver can be reversed? 23 demonstrate how much scar they've had. 24 24 A. That's a very good question, So some patients in these studies, 25 Counselor. 25 they'll have Stage 3 fibrosis on the biopsy. Page 187 Page 189 1 I'd -- I'd say that, yes, there's 1 They then undergo a bariatric surgery like a 2 very good evidence that a sufficient amount of 2 Roux-en-Y gastric bypass, which is very 3 effective in causing significant weight loss. 3 weight loss can lead to resolution of fat in 4 Like, a Roux-en-Y gastric bypass patient might 4 the liver. 5 So fat will leave the liver. lose 30 percent of their body weight over the 6 usually it's -- it's in the ballpark of 7 to course of a year. So they -- they definitely 10 percent of body weight that needs to be lost 7 achieve that benchmark of 10-percent weight to achieve fat coming out of the liver and, 8 loss. therefore, resolution of steatohepatitis or 9 If you take a patient like that and 10 then do a biopsy a year or two after they've 10 MASH or NASH. lost all that weight, sometimes their fibrosis 11 But it's important to state that 11 12 even if fat is -- is gone after significant 12 stage has gone from a three to two. 13 weight loss, the scar -- any damage that's 13 So we know that there's some 14 resulted from the process is still there. The 14 potential to improve fibrosis if the patient 15 scar does not -- does not reliably go away. 15 achieves a lot of weight loss. But -- but 16 Q. And that was going to be my next 16 it's -- it would be very unusual to go from Stage 3 to completely normal. That -- that 17 question. generally is not seen. 18 Is scarring or fibrosis of the 18 19 liver reversible? 19 Q. And then the same type of question 20 A. So it's actually a very interesting 20 for cirrhosis.

Is cirrhosis reversible to any

A. You're asking very -- really good

questions. These are questions that patients

21

22

23

24

degree?

25 ask all the time too.

21 area of -- of -- of research because generally,

23 fibrosis generally was not reversible. And --

25 accurate, but I think, you know, we're finding

22 you know, the canonical thinking was that

24 and for the most part, I think that's still

	Page 100		Dags 102
1	Page 190 Historically, we do we we	1	Page 192 correct?
2	don't usually once we make a diagnosis of	$\frac{1}{2}$	A. Yes.
3	cirrhosis, we regard the patient to have	3	Q. And would thrombocytopenia be an
4	cirrhosis moving forward, and we manage them	4	abnormal CBC result?
5	with the assumption that there is cirrhosis.	5	A. Yes, generally. Yeah. If the
6	There are some scenarios like very	6	platelet count's less than 150, that would be
7	specific scenarios, where patients may have	7	regarded to be an abnormal CBC.
8	some improvement in their their estimated	8	Q. I want to go back to your expert
9	fibrosis, very, very specific scenarios. And	9	report, which was Exhibit 1. I'll go ahead and
10	one scenario is Hepatitis C virus. That's	10	screenshare it, but feel free to look at it
11	probably the best studied one where a patient	11	yourself as well.
12	has chronic Hepatitis C. They develop	12	A. Okay.
13	cirrhosis, and then they're treated with a	13	Q. I want to go to page 18 right now.
14	medication that can cure the Hepatitis C	14	I, first, want to direct you to this part of
15	entirely.	15	your opinion, which is, "Cirrhosis refers to
16	Those medications were, you know,	16	significant scar tissue that impairs liver
17	developed in, like 2015, 2016. And so now	17	function."
18	we're able to cure Hepatitis C, and we've	18	You agree with that, correct?
19	observed over the past decade or so in	19	A. Yes.
20	following these patients, that some of those	20	Q. Okay. And that and that is what
21	patients might go from F4, which is cirrhosis,	21	Penn Medical is saying as well, correct, that
22	to F3.	22	it's both the scar tissue plus the impaired
23	The reason why I say it's a pretty	23	liver function?
24	exceptional circumstance is a lot of those	24	A. Yes.
25	patients the only reason the only cause of	25	Q. Okay. And then you start talking
	Page 191	,	Page 193
1	their liver disease was Hepatitis C, and	1	about FIB-4.
2	their liver disease was Hepatitis C, and there's a very abrupt abrupt and complete	2	about FIB-4. Is that what you were discussing
2 3	their liver disease was Hepatitis C, and there's a very abrupt abrupt and complete removal of that underlying cause of liver	2 3	about FIB-4. Is that what you were discussing earlier as far as being able to diagnose
2 3 4	their liver disease was Hepatitis C, and there's a very abrupt abrupt and complete removal of that underlying cause of liver disease. So that doesn't really translate	2 3 4	about FIB-4. Is that what you were discussing earlier as far as being able to diagnose cirrhosis with?
2 3 4 5	their liver disease was Hepatitis C, and there's a very abrupt abrupt and complete removal of that underlying cause of liver disease. So that doesn't really translate to to MASLD and MASH for the vast majority	2 3 4 5	about FIB-4. Is that what you were discussing earlier as far as being able to diagnose cirrhosis with? MS. ROSE: Objection to the form.
2 3 4 5 6	their liver disease was Hepatitis C, and there's a very abrupt abrupt and complete removal of that underlying cause of liver disease. So that doesn't really translate to to MASLD and MASH for the vast majority of patients where, you know, to achieve that	2 3 4 5 6	about FIB-4. Is that what you were discussing earlier as far as being able to diagnose cirrhosis with? MS. ROSE: Objection to the form. THE WITNESS: Yeah. Not not
2 3 4 5 6 7	their liver disease was Hepatitis C, and there's a very abrupt abrupt and complete removal of that underlying cause of liver disease. So that doesn't really translate to to MASLD and MASH for the vast majority of patients where, you know, to achieve that abrupt transition, you need to have substantial	2 3 4 5 6 7	about FIB-4. Is that what you were discussing earlier as far as being able to diagnose cirrhosis with? MS. ROSE: Objection to the form. THE WITNESS: Yeah. Not not not in and of itself to diagnose the
2 3 4 5 6 7 8	their liver disease was Hepatitis C, and there's a very abrupt abrupt and complete removal of that underlying cause of liver disease. So that doesn't really translate to to MASLD and MASH for the vast majority of patients where, you know, to achieve that abrupt transition, you need to have substantial and sustained weight loss, which unfortunately,	2 3 4 5 6 7 8	about FIB-4. Is that what you were discussing earlier as far as being able to diagnose cirrhosis with? MS. ROSE: Objection to the form. THE WITNESS: Yeah. Not not not in and of itself to diagnose the cirrhosis, but as a tool to risk
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2 3 4 5 6 7 8 9 10	their liver disease was Hepatitis C, and there's a very abrupt abrupt and complete removal of that underlying cause of liver disease. So that doesn't really translate to to MASLD and MASH for the vast majority of patients where, you know, to achieve that abrupt transition, you need to have substantial and sustained weight loss, which unfortunately, is very tough for patients to the achieve. MR. VAUGHN: Nina, I'm at a great spot for a break if you want to do lunch	2 3 4 5 6 7 8 9 10	about FIB-4. Is that what you were discussing earlier as far as being able to diagnose cirrhosis with? MS. ROSE: Objection to the form. THE WITNESS: Yeah. Not not not in and of itself to diagnose the cirrhosis, but as a tool to risk stratify risk stratify patients with chronic liver disease who may require further testing to to rule in or rule
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	Page 194		Page 196
1	is extremely unlikely to have advanced	1	positive predictive values.
2	fibrosis.	2	Q. And then you note that FIB-4
3	And as I stated previously,	3	between 1.3 and 2.67 are an intermediate range
4	advanced fibrosis, that I'm referring to F3	4	for advanced fibrosis and cirrhosis.
5	or F4 fibrosis, which I think I say a little	5	What is your basis for those
6	bit higher up in the paragraph.	6	numbers?
7	Q. Understood. And then you note, "A	7	A. Yeah. That that comes from
8	FIB-4 greater than 2.67 has an 80-percent	8	guidelines as well as the literature that I was
9	positive predictive value of having cirrhosis."	9	referring to in my previous response.
10	Can you explain that?	10	So basically, the FIB-4, we think
11	A. Sure. So if you calculate the	11	of there as being kind of three potential
12	FIB-4 in the same way that I just mentioned, if	12	buckets. Either it's very low, in which case
13	the value is over 2.67, what I mean by	l	you've effectively ruled out advanced fibrosis.
14	80-positive predicted value of having		It can be very high, in which case the patient
15	cirrhosis, if you had 100 patients and all 100		has a high risk of having advanced fibrosis or
16	had a FIB-4 over 2.67, around 80 of them would,	16	cirrhosis. Or it can be in this indeterminant
17	in fact, have cirrhosis.	17	range in between, which is sort of the gray
18	Q. And you noted, "A FIB-4 above 2.67		zone where the patient, you know, they they
19	denotes a very high risk of advanced fibrosis."	19	may have cirrhosis. They may have advanced
20	What is that based on?	20	fibrosis, but they need, you know, some
21	A. Right. So that's sorry. I'm	21	additional dedicated testing to clarify how
22	trying to see exactly where that is on on my	22	much scar tissue they may have.
23	screen as well.	23	Q. Is intermediate risk the same as
24	Yeah. Right. So I'm drawing a	24	moderate risk?
25	contrast there between the low FIB-4 value in	25	A. I'm not saying intermediate. It
-			
1	Page 195 the previous sentence where I'm just trying to	1	Page 197
1 2	the previous sentence where I'm just trying to	1 2	says indeterminate. So it can't be it can't
2	the previous sentence where I'm just trying to put into context what a low FIB-4 means in	2	says indeterminate. So it can't be it can't concretely stated based on the FIB-4, you know,
2 3	the previous sentence where I'm just trying to put into context what a low FIB-4 means in terms of negative predicted value and then	2 3	says indeterminate. So it can't be it can't concretely stated based on the FIB-4, you know, if they do or do not. They need further
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Page 198 Page 200 1 hepatologist. 1 FIB-4 scoring? 2 In the past few years, it's been 2 A. I was -- I can't recall the 3 codified in, you know, in different guidelines. 3 specific year, but, you know, I -- I've 4 You know, for example, the American College of 4 certainly been aware of it, you know, as long Gastroenterology -- sorry, American College of as I've been a hepatologist. Gastroenterology guidelines, you know, includes 6 But like I said, it was more FIB-4 in the diagnostic algorithm to identify 7 originally in the context of more Hepatitis C; patients who may have cirrhosis or need further and then subsequently when it was studied in the setting of MASLD and MASH -- I mean, it's 9 evaluation. 10 So -- so I can't give you precise 10 certainly has been much more prominent I would say in the past two to three years where it's 11 date; but the past few years, it's become much 12 more well-recognized and communicated in 12 been a central point of -- of our -- our risk 13 guidelines. 13 management and algorithmic denitrification of 14 And so this is a new methodology? cirrhosis at the population level. Q. 14 15 It's relatively new. I -- I Q. When did you start computing FIB-4 A. 15 scores as part of your practice? 16 think -- I -- I don't know when this 4 was 16 17 first published. I can't recall off the top of 17 A. I see. I've been routinely for at my head, you know, when the first -- or least a couple of years. 18 deriving this was published. 19 Q. What patient population do you use 19 20 But initially, it was more the FIB-4 score with? 20 21 specifically to the Hepatitis C literature. 21 A. I use it broadly, but some of the 22 And the way -- the reason why I say it's more 22 cutpoints differ a little bit depending on the 23 in the past couple of years is because it was 23 etiology of liver disease. You know, most of subsequently studied in detail in MASLD and 24 24 my patients these days -- in the Veterans 25 MASH patients. 25 Hospital is where I take care of a lot of Page 199 Page 201 1 And given that, you know, MASLD and 1 patients. 2 MASH is a -- is one of the predominant causes 2 Most of the patients have 3 of liver disease in the United States now, Hepatitis C alcohol or FIB-4 -- I'm sorry, or 4 it's -- it's been a priority to educate, you MASLD/MASH. Probably the majority have -- have 5 know, primary care physicians about using the 5 MASLD and MASH. 6 FIB-4. And somehow systems have gone so far as So those are the -- the settings 6 7 to integrate it into the medical records system where I primarily use it, but I'd say 8 to automatically calculate it and present it to predominantly Hepatitis C and MASH. a primary care to -- to prompt them to -- to 9 Do you know how the FIB-4 score was 10 take action and triage the patients 10 developed? 11 appropriately. 11 So I can provide you with my 12 Q. Are there still some facilities 12 recollection. I mean, I would have to find the 13 that don't do FIB-4? seminal studies to look at the methodology in 13 14 A. I mean, I'm sure there is -- you detail, but I can -- I'm happy to provide you 15 know, as with any guideline, there's practice with my general recollection of -- of the type 15 16 variation, you know, some practitioners that 16 of approach. 17 might not be following the literature or best 17 Q. Great. 18 practice state-of-the-art guidance. 18 Yeah. So similar to what I said, A. 19 I have no doubt that there are 19 the researchers that develop this score and 20 similar scores -- there are other scores 20 practitioners out there that don't know about 21 the FIB-4 or don't use the FIB-4; but, you 21 similar to this that have been developed.

51 (Pages 198 - 201)

22 Actually -- actually, I can probably be more

concrete because I know the person that developed this. It's Richard Sterling. He's a

25 hepatologist currently at BCU. Sorry. It's

24

24 guidelines.

25

22 know, nonetheless, it is the state-of-the-art

When did you first learn about

23 for medical practice. It's codified in our

Page 202 Page 204 1 coming to -- more recollection is coming to me 1 cutpoints for those patients for FIB-4, and 2 they identify what threshold beyond which are 2 as think about this because I'm remembering conversations that I've had with him. 3 we really well-separating patients that have 4 cirrhosis and what's the opposite case? It probably was developed some time 4 5 ago, but it might even have been, you know, a 5 What -- what low threshold are we really decade, honestly, when it was first developed. 6 adequately separating patients who clearly But regardless, Dr. Sterling, if I'm recalling 7 don't have cirrhosis. 8 this correctly, he -- he thought about, you 8 That's the general methodology know, labs that were plausibly related to 9 that -- that I, you know, I think was used in 10 cirrhosis first. AST, ALT, platelet count for 10 this case. But, you know, I haven't -- you 11 some reasons have articulated -- some that I 11 know, I haven't reviewed that particular study 12 in a long time, and I really can't recall 12 have yet to explain are important when you're 13 exactly what year it was. But the more I think 13 re-stratifying patients for cirrhosis. 14 I think I've explained the 14 about it, it must have been -- gosh, it might 15 relevance of platelet count, how that starts to 15 even have been a decade ago, if not more. I'm 16 go down when someone develops cirrhosis and 16 not sure. 17 elevated pressures in the portal system behind 17 Because I -- I had this 18 the liver. So platelets are very important. 18 conversation with Dr. Sterling. Sorry. Too 19 AST and ALT in the setting of much of an aside, but when I was interviewing 19 20 cirrhosis something interesting and unusual 20 for hepatology positions -- and that was in 21 happens -- not unusual, but something 21 2019, 2020, and so at that time I met with him; 22 interesting happens, where they -- the levels 22 and we discussed the FIB. 23 can actually start to go down over time. And 23 So it was clearly in prac- -- it 24 the AST in particular will start to rise 24 was clearly present at that time and likely for 25 relative to the ALT. So the ratio becomes. sometime prior. Page 203 Page 205 1 oftentimes, a little bit more skewed towards 1 Q. And does it matter how many 2 AST being a little bit higher than the ALT. patients it was initially studied in to be And so the score -- the formula 3 developed to? 3 4 that's used for this has a ratio of AST and 4 You he said it might have been a 5 ALT, and then it has platelets as a factor. I 5 hundred? 6 think it's multiplied by that. The square root MS. ROSE: Object to the form. 6 7 is in the formula somewhere, and then age 7 THE WITNESS: Yeah. I mean, sample 8 8 factors in. sizes matter to provide estimates of -- of 9 9 accuracy, diagnostic and predictive But that was the plausibility for 10 why those factors were important and they were accuracy of any store; but oftentimes, 10 11 hypothesized to be this way. it's more important are subsequent 11 So Dr. Sterling and colleagues, you 12 12 validation studies, where other 13 know, they -- they -- they started from that 13 researchers will take the tool or the 14 point about what factors were plausibly related 14 formula and apply it in their own cohort 15 and important, and then they, I think, fit a 15 of patients or in patients who have 16 variety of formulas from different types of 16 different types of liver disease. 17 models, I -- I expect and correlated that I alluded to that before that, you 17 18 against biopsy results in patients. know, Hepatitis C was one of the earliest 18 19 And then they identified -- okay. 19 use cases and most important use cases for 20 Let's say they had a patients. I'm not sure 20 FIB-4. But subsequently, there have been 21 how many they had in their initial study. But a variety of studies where FIB-4 has been 21 22 hypothetically, if they had a patients from 22 studied specifically in patients with 23 diverse degrees of scarring, some patients MASLD and MASH to identify the cutpoints 23 24 might have F4; some have F1; some have F2, 24 that I -- that I stated in my expert 25 et cetera. And they look at different report.

1	Page 206	1	Page 208
1	So so yeah. It's not I'm not	1	A. That is a good question. Some of
2	basing this on one study. There are a	2	the limitations of the FIB-4 index are you do
3	variety of different validation studies	3	need to interpret it in in the context of
4	across different patient contexts and	4	what's happening with the patient. For
5	different patient cohorts that inform the	5	instance and this is actually relevant in
6	diagnostic accuracy of these tools.	6	patients with alcohol-related liver disease.
7	BY MR. VAUGHN:	7	If they if a patient with
8	Q. At the time you met with	8	alcohol-related liver disease is very heavily
9	Dr. Sterling, was FIB-4 being used in that	9	drinking, that can cause the AST to rise more
10	MASLD patients, NAFLD patients?	10	than the ALT; and that can impact the validity
11	A. I honestly can't recall if it was	11	of the FIB-4 performance.
12	being used in MASLD and MASH patients at that	12	So it's it's best it's really
13	time.	13	best applied in scenarios where there's a
14	Q. Was there a time it wasn't being	14	stable baseline, you know, labs for patients.
15	used in those patients?	15	That obviously is less relevant for MASLD
16	A. I expect that you know, most	16	patients because by definition, they don't have
17	doctors, you know, practitioners they wait for	17	significant alcohol exposure. That's one
18	the studies of external validity or specific	18	context.
19	validity in different populations. So I I	19	The other context is sometimes the
20	expect that, you know, when it first came	20	platelet count can be invalidated in some
21	out and part of my recollection here is	21	patients where it no longer becomes a good
22	challenging because I wasn't a hepatologist at	22	proxy for portal hypertension and and liver
23	the time it was being used primarily. So it	23	disease and cirrhosis.
24	wasn't part of my practice obviously when I	24	The main context for that are
25	you know, prior to my hepatology practice.	25	things like if someone had their spleen
	Page 207		Page 209
1	But I expect there probably was a	1	removed, the platelet count rises
2	time where it was really primarily being used	2	substantially. And so they'll have a very
3	in Hepatitis C. It was only after, you know,	3	elevated platelet count. And so it's no longer
4	these validation studies in MASLD and MASH	4	reliable to use the FIB-4 in that type of
5	patients came out that there was increased	5	patient.
6	confidence and demonstration of cutpoints that	6	Or a patient that has some specific
7	can be reliably used in those patients.	7	autoimmune types of conditions that could
8	Q. And so are you not aware what	8	impact the platelet count. One instance is
9	patient population the FIB-4 index was	9	something called ITP, idiopathic idiopathic
10	initially developed with?	10	thrombocytopenia.
11	MS. ROSE: Object to the form.	11	So you have to understand, like,
12	THE WITNESS: As I said, you know,	12	the particular patient context to understand if
13	I I don't recall exactly. My my	13	the AST, ALT, and platelets are reliable for
14	recollection my loose recollection is,	14	the purpose you're trying to apply them.
15	you know, I believe it was primarily in	15	That those are the major limitations. And,
16	Hepatitis C patients, though, I'd have to	16	of course, you know, interpreting the
17	look back at literature and and check.	17	diagnostic accuracy. Like I said, it's not a
18	What I can say now in the current	18	hundred percent accurate for ruling in
19	state of practice, it is standard to apply	19	cirrhosis, which is why further testing and
20	this across multiple etiologies liver	20	corroboration is needed.
21	disease and definitely in patients with	21	But, you know, 80-percent positive
22	MASLD and MASH.	22	predictive value for a screening test is quite
23	BY MR. VAUGHN:	23	good.
24	Q. What are the limitations of the	24	Q. And so like you were saying, the
25	FIB-4 index?	25	platelet count makes a big determination in the

	Page 210		Page 212
1	final value of the FIB-4 score, correct?	1	extremes of age, patients become a little bit
2	A. Yes. I'd say so.	2	more likely to have higher scores. And
3	Q. And so it's very important to	3	generally, that's appropriate in in most
4	investigate any causes that might drop or	4	instances because, you know, the longer you've
5	increase someone's platelet count, correct?	5	been alive, the more likely it is you 'e
6	A. Yes. I'd agree with that.	6	accumulated more scar. And that's part of the
7	Q. And you mentioned Dr. Sterling is	7	reason why age is in there is my understanding.
8	the one who developed the FIB-4 index.	8	But there can be scenarios where if
9	Would you defer to him on the	9	a patient has not really been demonstrated to
10	specific weaknesses and strengths of the FIB-4	10	have longstanding, preexisting chronic liver
11	index?	11	disease and age is the driving factor for a
12	A. No, I wouldn't defer to him. I	12	FIB-4 being elevated. My suspicion is that
13	think that this is so widely used in hepatology	13	it's a little bit less accurate in that
14	practice now that, you know, I I was able to	14	setting.
15	kind of articulate to you very clearly, like,	15	Q. And in this case for Mr. Roberts,
16	multiple specific examples of limitations; and	16	how did scratch that. Sorry. I'm going to
17	that's informed directly by my clinical	17	get a drink.
18	experience using the FIB-4.	18	MS. ROSE: Your sickness has
19	So I think that because so many	19	finally caught up to you.
20	practitioners have experience using this in	20	MR. VAUGHN: No kidding.
21	practice, we understand the boundaries of, you	21	BY MR. VAUGHN:
22	know, when it's appropriate to apply, when you	22	Q. In this case for Mr. Roberts, how
23	need to be cautious, and things like that.	23	did you calculate the FIB-4 score?
24	Q. Do you believe that crashed	24	A. So I took his age at a
	that. Sorry.	25	particular at the time the lab was drawn. I
		1	
	Page 211		Page 213
1	Page 211 So you believe you have more	1	Page 213 took an AST and the ALT and the platelet score.
1 2	So you believe you have more	1 2	took an AST and the ALT and the platelet score,
2	So you believe you have more expertise in the FIB-4 index than Dr. Sterling?	2	took an AST and the ALT and the platelet score, and then I put it into yeah. We have tools
2 3	So you believe you have more expertise in the FIB-4 index than Dr. Sterling? MS. ROSE: Object to the form.	2 3	took an AST and the ALT and the platelet score, and then I put it into yeah. We have tools that we use in practice to that have these
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	Poses 214		Page 216
1	Page 214 A. I don't recall. I believe they're	1	Page 216 BY MR. VAUGHN:
2	the same one. It obviously looks	2	Q. I'll share the PDF version of this
3	different on so I don't have the let me	3	web page. It typically has a picture of him,
4	see. I think I can tell you if I have the app	4	but you can see down here is this the Richard
5	on my phone or not. That might help me answer	5	Sterling you are talking about?
6	the question. That's okay.	6	A. Yes.
7	I do have the app on my phone.	7	Q. Okay. And do you see up here at
8	There is an app on the phone. I don't honestly	8	the top where it says, "FIB-4 was developed in
9	remember if I navigated to the website or if I	9	patients with HIV and HCV coinfections"?
10	used the app. If I had to guess, I probably	10	A. Yes, I see that.
11	used the app because I used the app when I see	11	Q. And does that mean that the
12	patients.	12	patients that FIB-4 was developed in had both
13	So most likely I used the app, but	13	HIV and HCV?
14	my understanding is the formula and the	14	A. That yeah. That appears to be
15	computations would be the same if you used the	15	the case based on that sentence.
16	app versus going to the MDCalc website.	16	Q. Is that what "coinfection" means,
17	Q. All right. And you wrote your	17	you have both infections at the same time?
18	expert report just about a month ago, right?	18	A. Yeah. That typically means you
19	A. I believe so, yes. Yeah.	19	have both infections.
20	Q. And the website you're referencing	20	Q. And what is HCV?
21	that has it, is that Dr. Sterling's website?	21	A. Yeah. So HCV, that's what I
22	A. No, that's not Dr. Sterling's	22	referring to previously. It stands for
23	website. MDCalc is maintained I'm not sure	23	Hepatitis C virus HCV I think I mentioned
24	exactly maintains it, but it's it's some	24	earlier that my recollection was it was
25	organization that they take well-validated	25	initially derived in patients with HCV as their
	Page 215		Page 217
1	scores that are used for prediction models or	1	chronic liver disease. So that's what HCV is.
$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	re-stratification models from many different	1 2	chronic liver disease. So that's what HCV is. Q. But in actuality, it's people with
_ ا	re-stratification models from many different fields, you know, cardiology, liver disease,		Q. But in actuality, it's people with HCV and HIV at the same time, correct?
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	re-stratification models from many different fields, you know, cardiology, liver disease, you know, oncology, all sorts of different fields. They identify scores that have been well-studied and validated, and then they typically reach out to authors who published them to get their permission to put there formula onto the site and then the you know, code it basically to facilitate a centralized resource to to to help with broad usage of a validated tool. That's usually their process. Q. Understood. So when you were saying app or website, you meant MDCalc has a website and an app? A. Yes. Q. Understood. A. Yes, yes, yes. Sorry. That was unclear. MR. VAUGHN: All right. Kathryn, can you drop in the FIB-4 web page for	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. But in actuality, it's people with HCV and HIV at the same time, correct? A. Sure. Yeah. I yeah. I neglected to recall I mean, HIV is not a cause of chronic liver disease, so that's why I emphasize the HCV aspect of it. But yes. Yeah. I agree. It says, it was developed in HCV patients who were co infected with HIV. Q. Does HIV in impact the blood? A. It can impact blood counts, yes. Q. Such as platelets? A. It primar so I'll caveat this by saying that I'm not an infectious disease doctor with specific expertise in HIV but it primarily impacts white blood cells, in particular CD4 blood positive lymphocytes. That's why you may or may not have heard about CD4 counts, but that's the main thing that is tracked for patients with HIV. And that's also what's used to define potential aids. Acquired

		Ι	
1	Page 218 Q. And just to be clear to the jury,	1	Page 220 Yes. I'm okay with that
2	HIV is what eventually can turn into AIDS,	$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	characterization. Yeah. So they they it
3	correct?	3	looks like they use a different schema for
4	A. Yes. So HIV is human	4	classifying fibrosis. There's I've been
5	immunodeficiency virus. And HIV in many	5	referring to something called the METAVIR
6	patients, if it's untreated, can progress to	6	staging, which goes from 0 to 4. It looks like
7	AIDS, acquired immunodeficiency syndrome.	7	what he's using is something called the Ishak
8	Q. And Mr. Roberts did not have HIV or	8	framework, which ranges from 0 to 6, but it's
9	AIDS, correct?	9	the same principle that there's progressive
10	A. Correct. He did not have HIV as	10	fibrosis that you can break into, you know,
11	far as I know. He did not have Hepatitis C	11	stages of fibrosis.
12	virus.	12	Q. But you're saying a FIB-4 score of
13	Q. Okay. And then Dr. Sterling has a	13	0 to 2 is mild fibrosis?
14	section here about what perils, pitfalls,	14	A. Oh, I see.
15	and/or tips do you have for users using the	15	Q above, correct?
16	FIB-4?	16	A. No, no, no, no. Let me clarify.
17	A. Okay. I see it.	17	That's not what he's saying there.
18	Q. Okay. And he says, "It was	18	He's not giving you the interpretations of
19	developed in a cohort of subjects that did not	19	ranges of the FIB-4 score. He's giving you
20	include the young or very old, so it might not	20	biopsy pathology stages of fibrosis there.
21	perform as well in those populations, given	21	Q. How do you convert, then, the FIB-4
22	that the age is the numerator. Furthermore,	22	score to the Ishak levels?
23	inclusion of age makes it less reliable to	23	A. So when you asked me to describe
24	loose use longitudinally."	24	the process of how they derived the score,
25	What does what does that mean:	25	this what's being described here is actually
	Page 219		Page 221
1	"Less reliable to use longitudinally"?	1	entirely consistent with what I was describing.
2	A. "Longitudinally" refers to just	2	They did biopsies in patients.
3	over time.	3	They've looked at the liver biopsies of
4	So I I don't know necessarily the full context of what he refers to there.	4	patients, and they used this Ishak scoring criterion to determine how much fibrosis there
5	But, you know, if you were to track FIB-4 I	5	was on the biopsies, and that's what's shown
6 7	don't know over the course of, like,	6 7	there in the area you have highlighted.
8	multiple decades, as someone, you know,	8	So Ishak levels, Ishak Stage 0 to 2
9	progresses into old marriage, perhaps his		is mild fibrosis. Ishak stage 3 to 4 is
10	perception is that it impacts the reliability	10	moderate. Ishak Stage 5 to 6 is severe
11	of it.	11	fibrosis/cirrhosis.
12	Q. And is that because age alone could	12	So they've gathered that for all
13	make your FIB-4 abnormal?	13	the patients in their in their study, and
14	A. Yes. I think I stated that	14	then they computed the FIB-4. And they used
15	previously that, you know, someone who is very	15	the distribution of FIB-4 scores and compared
16	old, just on on you know, on the basis of	16	those to the biopsy results to identify, among
17	age alone, they can have an elevated FIB-4.	17	the patients with severe fibrosis and
18	Yes.	18	cirrhosis, what were the ranges of FIB-4 scores
19	Q. And then up here he notes that	19	that would help segregate those individuals,
20	FIB-4 between 0 and 2 is mild fibrosis.	20	you know, in into a category as best as
21	Do you agree with that?	21	possible. They did the same thing for the mild
22	A. Sorry. Let me look back at this	22	fibrosis side.
23	again. Sorry.	23	Does that make sense?
24	FIB-4 was developed to correlate	24	Q. Are you saying the 0 to 2 here is
25	with Ishak levels.	25	not talking about the FIB-4 score?

	D 422		P. 224
1	Page 222 A. No. That that there is	1	Page 224 the MDCalc at the top. I didn't even realize
2	referring to the biopsy fibrosis staging.		it was the same web page that you were talking
$\frac{2}{3}$		$\begin{vmatrix} 2 \\ 3 \end{vmatrix}$	about.
4	Q. And so how do you convert from a FIB-4 score to that?	4	A. This was the
5	A. So it might be most clear if you	5	MS. ROSE: Mr. Vaughn, I'm sorry to
6	were to literally put numbers into the	6	interrupt. But if we're going to the
7	calculator.	7	if you're going to ask questions about
8	Q. All right.	8	this website, I'd like it to be introduced
9	A. So when you put the numbers into	9	as an exhibit so we have a record of it.
10	* *	10	MR. VAUGHN: That was that was
11	count, it will give you a result. That result	11	the exhibit I just introduced. He wanted
	is what the FIB-4 score is, and it will give	12	to do
13	you an interpretation of, you know, which	13	MS. ROSE: Oh.
14	fibrosis stage that patient is likely to have	14	MR. VAUGHN: He wanted to do the
15	on the basis of their FIB-4 score?	15	calculations, and so I'm using it as a
16	Hopefully, that makes sense.	16	calculator strictly to see if it works.
17	As I was saying, I mean, there	17	He wanted to see it to do the
18	there have been different validation studies	18	calculations.
19	done in different etiologies of liver disease.	19	MS. ROSE: Right. Is this a
20	So even though it was developed originally in	20	different page than was previously
21	Hepatitis C population with co-infected HIV.	21	introduced.
22	It has subsequently been studied specifically	22	MR. VAUGHN: It's the exact same
23	in patients with MASLD and MASH in a similar	23	page I just introduced as an exhibit.
24	fashion to identify the relevant cutpoints for	24	MS. ROSE: Oh, okay. Apologies.
25	· · · · · · · · · · · · · · · · · · ·	25	Apologies.
	Page 223		Page 225
1	citing in my expert report.	1	MR. VAUGHN: You're okay.
2	I site, you know, some specific	2	MS. ROSE: It looked like a
3	studies that identify those cutpoints and how	3	different page.
4	you can map the FIB-4 score for MASLD MASH	4	MR. VAUGHN: It does look different
5	patient to the pathology on on biopsy.	5	because when I printed it off, it you
6	Q. I'm going to go to the actual web	6	couldn't see his picture. So it made it
7	page right now so we can actually use the	7	look different.
8	calculator and see if it's accurate on	8	MS. ROSE: Okay. Thanks for the
9	Dr. Sterling's web page.	9	clarification.
10	A. Sorry. I don't mean to interrupt	10	MR. VAUGHN: You're fine.
11	you, but just to clarify, this is not	11	BY MR. VAUGHN:
12	Dr. Sterling's web page. This is MDCalc. This	12	Q. All right. So in your expert
13	is the resource that I was ref that I was	13	report this is page 7, I think is the first
14	telling you about that	14	time I see you doing the FIB-4 score; is that
15	Q. Oh, okay.	15	correct?
16	A that is so whenever they	16	A. I
17	this is a very, very commonly used application,	17	Q. No. You did some earlier,
18	you know, website for for clinicians. His	18	actually. You do one on page 6 it looks like.
	picture is there because they feature the	19	A. Yes, I did.
19			Q. Okay. And do you know how old he
20	inventor of the tool; and this this this	20	
20 21	formula and site is made in his consent and in	21	would have been at that time in 2009?
20 21 22	formula and site is made in his consent and in collaboration with him. But Dr. Sterling does	21 22	would have been at that time in 2009? A. Sorry. I'd have to do the math.
20 21 22 23	formula and site is made in his consent and in collaboration with him. But Dr. Sterling does not own MDCalc. There are hundreds and	21 22 23	would have been at that time in 2009? A. Sorry. I'd have to do the math. So he was 64 when he passed away.
20 21 22	formula and site is made in his consent and in collaboration with him. But Dr. Sterling does	21 22	would have been at that time in 2009? A. Sorry. I'd have to do the math.

	Page 226		Page 228
1	Q. Let's see what the numbers come	1	Q. Okay. And right before your
2	out. So 56 and then his AST at this time was	2	expert sorry. Scratch that.
3	69, correct?	3	In your expert report, the
4	A. Yes.	4	preceding paragraph notes that he had elevated
5	Q. ALT was 112. And platelet count	5	liver levels ever since he was a teenager,
6	was 174.	6	correct?
7	MS. ROSE: Can I ask a question	7	A. Yes.
8	I'm sorry. This is for my own	8	Q. And then it says probably has fatty
9	clarification.	9	liver.
10	MR. VAUGHN: Uh-huh.	10	My is fatty liver more
11	MS. ROSE: Have these levels that	11	indicative of NAFLD or NASH?
12	you're putting it in, are you putting it	12	A. So just to I think I explained
13	in for a specific date where the	13	this previously, but just to rehash a little
14	MR. VAUGHN: Well, if you go	14	bit, fat in the liver, you'd have to determine
15	correct. If you go to page 6 of his	15	why there's fat. The main reasons for fat to
	expert report	16	be there are either alcohol or obesity.
16 17	MS. ROSE: Okay.	17	I think we agreed that he
18	MR. VAUGHN: towards the bottom		doesn't Mr. Roberts doesn't really have any
19	he lists the labs out that he used to	19	significant, you know, regular alcohol use
20	determine the FIB-4 score.	20	chronic history. So it doesn't appear to be
l		20	from alcohol.
21 22	MS. ROSE: Thank you. And and	22	So his fat in the liver is almost
23	we've established the age of the patient at this time?	l	
		l .	certainly related to MASLD, but the
24	BY MR. VAUGHN:	l .	determination of the MASH part is do we think
25	Q. Take your time, Doctor, and let me	23	there's inflammation accompanying the fat in
1	Page 227	1	Page 229
1	know what age you think I should be entering	1	the liver.
2	here.	2	And so the fact that he had
3	A. You're probably close. Well, let's	3	elevated liver numbers, AST to ALT, the
4	see. So I I you know, from my	4	transaminases, that is the evidence that
5	recollection, I got it from, like, the clinical	5	there's inflammation happening with the fat
6	notes at the time so but I didn't write it	6	because when there's inflammation in the liver,
7	down every single time.	7	that causes some injury to liver cells.
8	So he was 64 when he died in	8	AST and ALT are enzymes that are
9	2020 2020. So how much do I have to	9	present inside liver cells. Inflammation
10	subtract from that?	10	causes injury to liver cells, and those AST and
11	This this one sorry. I'm	11	the ALT, they spill out of the cells into the
12	just trying to scroll through here. So this	12	blood.
13	was the value from 2009. So 11 minus 6 64	13	So whenever we see AST and ALT
14	minus 11, I think 53. Try 53. It's either 53	14	elevated, that's an indication that something
15	or 54 most likely. Yeah.	15	will is causing inflammation and injury to the
16	Q. Okay. That 53 comes out to the	16	liver, but it doesn't tell you what. You have
17	number you've got. There you go because you've	17	to do more investigation to figure out what is
18	got a FIB-4 of 199.	18	the thing that is causing the injury. So you
19	So this is the formula you were	19	have to rule out Hepatitis C. You ruled out
20	using to get there, correct?	20	Hepatitis B. You have to rule out alcohol.
21	A. Exactly. So that was the exact	21	If you think it's MASLD or MASH,
	process I used. I got his age. I looked at	22	you have to demonstrate that there's fat in the
22			
22 23	his labs on a particular date. I plugged these	23	liver, and you typically look for other
22 23 24	into this calculator to get the values, and I	23 24 25	liver, and you typically look for other metabolic comorbidities, like diabetes, high blood pressure, high cholesterol, and obesity.

	Page 230		Page 232
1	And then you make your assessment through this	1	THE WITNESS: Well, yes. I mean,
2	process of ruling out other explanations for	2	it's a composite of all the factors you
3	the elevated AST and ALT and then ruling in the	3	put in.
4	likelihood of MASLD.	4	But I understand what you're saying
5	Q. Can you have elevated AST or ALT	5	that the only change you changed was the
6	without inflammation in the liver?	6	age, and you see how much the FIB-4 score
7	A. Yes, you can.	7	changes. But in my I guess two things
8	Q. And Mr. Roberts had elevated AST	8	that I think are important to highlight
9	and ALT since he was a teenager reportedly,	9	are, one, as you stated to me from
10	correct?	10	Dr. Sterling, this was not specifically
11	A. Yes.	11	studied in very young patients; but this
12	Q. Okay.	12	also makes clinical sense because I
13	A. Let me clarify one thing. I	13	wouldn't expect an 18-year-old to have had
14	apologize, Counselor.	14	sufficient time to develop advanced
15	You can have elevated transaminases	15	fibrosis and cirrhosis in the presence of
16	that separate from inflammation, but that's	16	MASH. It takes time to get cirrhosis.
17	mostly related to AST. ALT's actually very	17	So it's it's appropriate in this
18	specific to the liver.	18	regard that a very young patient, they
19	The the context there is that	19	have a very, very low probability of
20	AST is also produced in other areas of the	20	having cirrhosis in the setting of chronic
21	body, like in muscle, for example.	21	liver disease in general.
22	So in ALT being elevated is very,	22	BY MR. VAUGHN:
23	very strongly associated with inflammation	23	Q. But the patient you're talking
24	specifically in the liver. It's really the	24	about, if they had those same labs their entire
25	AST, if that is abnormal, that's not as much of	25	life, they would eventually show that they have
	Page 231		Page 233
1	a guarantee to be related to the liver.	1	fibrosis on the FIB-4 score when they got old
2	So I just wanted to clarify that.		· -
_	20 Tjust Wallet to Clarify that	l 2.	enough, correct?
3	I apologize.	$\begin{vmatrix} 2 \\ 3 \end{vmatrix}$	enough, correct? MS. ROSE: Object to the form.
3 4	I apologize. O. Thank you. And earlier you were	3	MS. ROSE: Object to the form.
4	Q. Thank you. And earlier you were	3 4	MS. ROSE: Object to the form. THE WITNESS: Sorry. Clarify that
5	Q. Thank you. And earlier you were talking about age was a big component of the	3 4 5	MS. ROSE: Object to the form. THE WITNESS: Sorry. Clarify that one more time, Counselor.
4 5 6	Q. Thank you. And earlier you were talking about age was a big component of the FIB-4 score, correct?	3 4 5 6	MS. ROSE: Object to the form. THE WITNESS: Sorry. Clarify that one more time, Counselor. BY MR. VAUGHN:
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1	Page 234		Page 236
1	So this is really just looking at	1	that someone has cirrhosis or not so we
2	age as a function of fibrosis, correct?	2	can figure out the next best step and
3	MS. ROSE: Object to the form.	3	management for that patient, which
4	THE WITNESS: No, it's not because	4	oftentimes may involve further testing to
5	those if you were to take if you	5	confirm or deny a diagnosis of cirrhosis.
6	were to put in, you know, normal AST and	6	But yes, I think the score this
7	ALT and normal platelet values and then do	7	score and and other types of scores
8	the same thing with age, you would not see	8	like this rely on the assumption that
9	the same thing.	9	chronic liver disease takes time to cause
10	So I mean, if you were to change	10	injury and scarring in the liver, and you
11	the AST here to, I don't know, 23 and the	11	have to progress through the stages.
12	ALT to 25 or something, which are normal	12	That's just part of the underlying
13	values, and give, you know, the platelet	13	understood physiology of
14	count of 230, which are very, very normal	14	pathophysiology of how cirrhosis develops.
15	range values for an individual, I'd expect	15	You progress through fibrosis stages to
16	you'd have a low FIB-4.	16	get there, and generally that takes time.
17	So it's not it's the entire	17	BY MR. VAUGHN:
18	score. You have to interpret all the	18	Q. And so that I put in age 30 now.
19	inputs together.	19	So even if he was age 30, he would
20	It this makes perfect clinical	20	just be a 1.12 at this time on the FIB-4?
21	sense that somebody with those labs, if	21	A. I agree. That's what it says.
22	if, in fact, someone went from 18 years	22	Q. Okay. If and if he goes up to
23	old with an AST and ALT that were	23	age 40, he's now at 1.5?
24	chronically elevated in the 60-to-100	24	A. Yeah.
25	range, if they had those labs from age 18	25	Q. And at age 50, now he hits the
23		23	
1	Page 235 to age 53, they would, in fact, have a	1	Page 237 1.87.
2	very high likelihood of having cirrhosis	2	So at age 50 is when you would
3	because that chronic liver disease had		=
		3	think he now has fibrosis: is that correct?
		3	think he now has fibrosis; is that correct? A. Well, like I said, fibrosis it
4	been present for a long enough amount of	4	A. Well, like I said, fibrosis it
4 5	been present for a long enough amount of time to progress through the fibrosis	_	A. Well, like I said, fibrosis it progresses through stages. I mean, he likely
4 5 6	been present for a long enough amount of time to progress through the fibrosis stages. And that's what this risk score	4 5	A. Well, like I said, fibrosis it progresses through stages. I mean, he likely had more mild fibrosis earlier in his life.
4 5 6 7	been present for a long enough amount of time to progress through the fibrosis stages. And that's what this risk score is is communicating.	4 5 6 7	A. Well, like I said, fibrosis it progresses through stages. I mean, he likely had more mild fibrosis earlier in his life. And at this point, you know, based on the
4 5 6 7 8	been present for a long enough amount of time to progress through the fibrosis stages. And that's what this risk score is is communicating. That's the main reason why age is	4 5 6	A. Well, like I said, fibrosis it progresses through stages. I mean, he likely had more mild fibrosis earlier in his life. And at this point, you know, based on the hypothetical scenarios you're putting into the
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	D 220		D 040
1	Page 238 now get a FIB-4 score 1.5, is it likely that he	1	Page 240
$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	has fibrosis at that time?	2	MR. VAUGHN: You're right.
1		l	Exhibit 8. Thank you, Nina.
3	A. Yes, it's likely that the patient	3	(Whereupon, Exhibit 8, Medical
4	has fibrosis. And so actually, if you look at	4	Record, Bates labeled Restricted
5	the interpretation just below the 1.50	5	Confidential Information
6	Q. Uh-huh.	6	GRobertsJr-CA-000659, was marked for
7	A you see that the approximate	7	identification.)
8	fibrosis stage is Ishak 2 to 3. And so that is	8	BY MR. VAUGHN:
9	what corresponds to what you were pointing to	9	Q. Do you see this platelet count is
10	previously about 0 to 2, 3 to 4, 5 to 6.	10	174, and the doctor's actually circled the
11	That's what you would expect to see.	11	platelet count?
12	If you were to do a biopsy in this	12	Does that mean the doctor is
13	hypothetical patient, you would expect that	13	looking specifically to see what his platelet
14	they would probably have fibrosis somewhere in	14	count is?
15	the intermediate range.	15	MS. ROSE: Object to the form.
16	Q. Okay. So when he was 18, the same	16	THE WITNESS: I I don't know who
17	labs, would he have fibrosis then based on your	17	circled that or what you know, what
18	assessment?	18	they would have been thinking when
19	A. Yeah. So I mean, based on FIB-4	19	circling it. So it's impossible for me to
20	alone, again, I you know, we we don't	20	say.
21	rely on FIB-4 exclusively. We look at the	21	BY MR. VAUGHN:
22	composite of multiple things.	22	Q. Understood. Is that a normal
23	But so with that stated, if I were	23	platelet count, in your opinion?
24	to just look at the FIB-4 here, he's likely to	24	A. It is on the very low end of
25	have, you know, minimal to no fibrosis. I	25	normal.
	Page 239		Page 241
		l	Fage 241
1	mean, so the estimate there is Ishak 0 to 1.	1	Q. And the reference range for this
1 2		1 2	
	mean, so the estimate there is Ishak 0 to 1.		Q. And the reference range for this
2 3	mean, so the estimate there is Ishak 0 to 1. So zero would be no fibrosis. One would be	2	Q. And the reference range for this lab for platelets, the bottom end range is 140,
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	Page 242		Page 244
1	must have just written that down when I was	1	And do you see how this lab, the
2	looking through the note. I think I was trying	2	low end of the reference range has now dropped
3	to be comprehensive in in accumulating the	3	to 130 as opposed to 140?
4	different comorbidities that he had across the	4	A. Yes, I see that.
5	medical record. And so if there was a new	5	Q. And no diagnosis was given for
6	diagnosis that was mentioned, I made an effort	6	thrombocytopenia at this time by his doctors;
7	to write that in just for completeness.	7	is that correct?
8	So, you know, it's it's relevant	8	A. I don't think I don't recall
9	to know if someone has GERD because it's	9	his I think Dr. Sanders had been ordering
10	another thing that is associated with obesity.	10	these labs, from my recollection, because I'm
11	So, you know, I don't think it's necessarily	11	looking at my report as well.
12	directly relevant to him developing	12	I don't think at this time the
13	hepatocellular carcinoma, but it's important in	13	platelet count was discussed with him.
14	this context to understand that the burden of	14	Q. Were you aware when you were
15	comorbidity that Mr. Roberts had that was	15	writing your expert report that the reference
16	likely associated with his degree of obesity.	16	range for this lab was 130 for the low end?
		17	A. Yeah. I did see that.
17	Q. Okay. So you didn't need to do any	18	
18	research into proton-pump inhibitors, correct?	l	
19	A. For the purpose of this case, no, I didn't I didn't look in detail at relevance	19	me.
20		20	And you didn't mention in your
21	of a proton-pump inhibitor for this case.	21	expert report what the reference ranges were
22	Q. And then the next FIB-4 you did, it	22	for the labs, correct?
23	looks like was at this November 4th, 2015, with	23	A. No, I didn't, but I have already
24	the following labs: AST 65, ALT 78, and	24	provided you with the context that in the field
25	platelet count 137.	25	of hepatology and informed by, you know,
1	Page 243	1	Page 245
1	And you're diagnosing him yourself	1	multiple hepatology guidelines, the platelet
2	now as thrombocytopenic, correct?	2	count of less than 150 interpreted in the
3	A. Correct, yes.	3	proper context has significance with respect to
4	Q. Okay.	4	cirrhosis and elevated portal pressures. And
5	MR. VAUGHN: And, Kathryn, can we	5	that's why I specifically noted in my report in
6	go ahead and do those labs now. This will	6	the parenthetical that thrombocytopenia is
7	be Exhibit 9.	7	defined by platelets less than 150.
8	(Whereupon, Exhibit 9, Medical	8	So I I took the time to write
9	Record, Bates labeled Restricted		that out because I acknowledge that the
10	Confidential Information		reference range here would make that appear
11	GRobertsJr-AMG-000051 through Restricted	11	with within the normal range of this lab.
12	Confidential Information	12	It wouldn't get flagged as being low. But to
13	GRobertsJr-AMG-000053, was marked for	13	me as a hepatologist, that's clearly abnormal.
14	identification.)	14	Q. And you're using the low platelet
15	MS. AVILA: Yes. It should be in	15	count to support your opinion that he had
16	there now.	16	portal hypertension at this time?
17	BY MR. VAUGHN:	17	MS. ROSE: Object to the form.
18	Q. Doctor, do you see here,	18	THE WITNESS: It's it would be
19	August 19th, 2009.	19	consistent with him developing portal
20	Oh, did I do the wrong one?	20	hypertension. Yes.
21	A. Yeah.	21	Again, I don't rely on just one
22	Q. I totally did. Sorry about that.	22	data point to make these determinations.
0.0	A (TC)1 (1 11 1 1)		
23	A. That's all right.	23	I looked at multiple data points wherever
23 24 25	A. That's all right. Q. November 4th, 2015, CBC and the platelet count is now 137.	23 24 25	possible. So he doesn't have a CT scan, for

	D 246		D 240
1	Page 246 instance, at that particular time point.	1	take care of. I think very carefully
2	He gets one five months later, which does	2	about the platelet count in particular
3	corroborate that he does have portal	3	because I know that you have to be mindful
	hypertension.	4	of interpreting that in the context when
5	· ·	5	
6	So in my view, I'm concerned that	6	you compute a FIB-4.
7	this patient is developing portal	7	And as I mentioned, just to bring back one specific point, a lot of the
8	hypertension and may already have, likely	8	veterans I had taken care of, alcohol is,
9	already has portal hypertension. But I would have done more investigation. If I	9	unfortunately, a big problem. And if
10		10	
11	was his treating physician at that time, I	11	patients are heavily drinking alcohol,
12	would have tried to do more investigation to confirm that.	12	that can suppress the bone marrow, that
1	BY MR. VAUGHN:	13	can suppress the platelet count.
13 14			So yes. I consider that too. And
	Q. And and in writing your report	14	as we've already talked about, Mr. Roberts
15	and coming to your expert opinion, did you into	15	didn't seem to be a heavy drinker. You
16	any other patient-specific factors specific to	16	know, there's no consistent mention of him
17	Mr. Roberts that could have explained this drop	17	heavily using alcohol.
18	in platelet counts?	18	There are other features on his lab
19	A. I did.	19	tests that make significant alcohol use
20	MS. ROSE: Object to the form.	20	unlikely too, but yes, I thought about all
21	THE WITNESS: I'm sorry.	21	those different things when I was
22	MS. ROSE: No that's okay. Go	22	interpreting his platelet count.
23	ahead.	23	BY MR. VAUGHN:
24	THE WITNESS: So yes, I did. So I	24	Q. What medications are you aware of
25	considered some of the factors that I've	25	that can decrease someone's platelet count?
1	Page 247	1	Page 249
1	already mentioned to you.	1	A. There are certain antibiotics. For
2	Did he have his spleen removed? He	2	instance, you know, one particular one is
3	did not.	3	bactrim or trimethoprim, sulfamethoxazole
4	Did he have immune thrombocytopenic	4	that's associated with low platelet counts.
5	purpura, ITP? He did not.	5	There are some immunomodulator
6	I've looked at medication-related	6	medications that are that are known to
7	causes. I remember specifically looking	7	suppress the platelet count and impact the CBC
8	through Dr. Sanders' medication list. And	8	generally. There are things like ASO
9	because there are some medications that	9	diaphragms. There's a range of different ones,
10	can sometimes cause low platelets, I did	l	but the medications that he was on at the time,
11	not identify any obvious offenders that	11	which I I can't exhaustively tell you the
12	would that be associated with a low	12	list off the top of my head, but I did review
13	platelet count.	13	the medications that he was taking to see if
14	And then I looked at the overall	14	they were plausibly linked to his platelet
15	trend as well because there are some	15	count being low.
16	patients that have you know, there	16	Q. When you say you reviewed the
17	there are different types of inborn kind	17	medications that he was taking to see if there
18	of mutagenic base conditions where they	18	was a link plausible link to his platelet
19	always have a low platelet count, but	19	count being low, were you just going off of the
20	that's clearly not the case for	20	current knowledge you had of what medications
21	Mr. Roberts either because his platelet	21	could lower someone's platelets?
22	count was normal. And then it downtrended	22	MS. ROSE: Object to the form.
23	to the point where it was abnormal.	23	THE WITNESS: Yeah. I'd say that
24	And so I considered all those	24	my current knowledge is informed by the
25	factors as I would for any patient that I	25	experience using medications and taking

	5 46		5 00
1	Page 250 care of patients who are on many of these	1	Page 252 Q. What relevance would there be
1	· · · · · · · · · · · · · · · · · · ·		
2	very common medications. And that's	2	MS. ROSE: Mr. Vaughn? MR. VAUGHN: Yeah.
3	usually based on a review of a resource	3	
4	such as UpToDate, which is a a medical	4	MS. ROSE: Sorry. I don't want to
5	resource where you can look up a wide	5	interrupt you while you're
6	variety things that are pertinent to to	6	MR. VAUGHN: It's okay.
7	practitioners across lots of different	7	MS. ROSE: on a role. But I
8	disciplines, but it includes very detailed	8	just wanted to note it's been about an
9	summaries of medication profiles, dosing	9	hour so if you
10	ranges, indications, adverse effects,	10	MR. VAUGHN: Oh. I'll wrap up very
11	contraindications, things like this.	11	quickly.
12	You know, and that oftentimes	12	MS. ROSE: Okay. Great.
13	includes, you know, for medications, what	13	BY MR. VAUGHN:
14	is the the what proportion of	14	Q. If his platelet were to go up at
15	patients may have issues with blood counts	15	some point later, what would that indicate to
16	or or you know, thrombocytopenia	16	you?
17	things of that nature.	17	A. Well, it's it's hard to to
18	So so yes, it's based on my	18	know. I mean, there's a lot of potential
19	knowledge, but my knowledge is informed	19	reasons why the platelet count could go up, and
20	by, you know, years of that kind of	20	so it would be very dependent on the particular
21	research and interaction with the medical	21	context in which it might be elevated. So it's
22	literature and medical resources.	22	hard to answer that specific hypothetical.
23	BY MR. VAUGHN:	23	I mean, you know, for instance,
24	Q. As you were drafting your expert	24	someone could be actively infected, and, you
25	report for Mr scratch that.	25	know, they've been to a hospital and their
	Page 251		Page 253
1	As you were drafting your expert	1	7 6 1
2	report, did you run each of Mr. Roberts'	2	7 1
3	medications through UpToDate to see if they	3	context understanding what's happening to the
4	could have an impact on his platelets?	4	platelet count in a patient like that.
5	A. I probably did not run each one	5	So yeah. So it's hard to say
6	through UpToDate. I I recall running	6	without kind of more specific details of what a
7	some of them, the ones that I may have had	7	hypothetical might be, but there are so many
8	lesser certainty about.	8	things that can affect platelet count.
9	But as I said, a lot of the	9	Q. So just specific to Mr. Roberts, no
10		10	other facts change, but let's say later on his
11	very commonly encountered in the setting of	11	platelet count returns to normal.
12	patients with MASH MASLD and MASH, and	12	Would that be indicative of
13	diabetes medications, medications for high	13	anything to you?
14	blood pressure, et cetera.	14	MS. ROSE: Objection to form.
15	So you know, I I relied on my	15	Incomplete hypothetical.
16	existing familiarity in some sense in some	16	THE WITNESS: Yeah. That's right.
17	sense to to make that adjudication. But	17	I agree. It's a tough hypothetical to
18	additionally, like I said, I never in isolation	18	answer.
19	looked at the platelet count. I'm looking at	19	But platelet counts fluctuate, and
20	the platelet count in the context of the trend	20	this is why I keep emphasizing the trend.
21	and other corroborating information that help	21	If I were to check someone's platelet
22	me understand why the platelet count might be	22	count in the morning and then check it the
23	dropping. So that's that's the way I	23	next day, it's not going to be the exact
24	approached my review of this area of his	24	same value. These are always in
	record.	25	fluctuation.

1	Page 254	4	Page 256
1	So the trend in the platelet count	1	(Whereupon, a break was taken.)
2	is also important to to understand as	2	THE VIDEOGRAPHER: We are back on
3	well as the the milieu of other	3	the record at 2:45.
4	clinical data, imaging data in the patient	4	BY MR. VAUGHN:
5	context, whether or not chronic liver	5	Q. All right. Doctor, I'm going to
6	disease is there and and what the	6	admit Exhibit 9.
7	pretest probability is for cirrhosis.	7	MR. VAUGHN: Kathryn can, you drop
8	So so I'm not overly fixated on	8	the 2018 adverse effects of proton-pump
9	the platelet count alone. I'm I'm	9	inhibitors on platelet count.
10	looking at the platelet count and its	10	MS. AVILA: Yes. And I think it's
11	trend in the context of the entire	11	Exhibit 10.
12	clinical picture.	12	MR. VAUGHN: Exhibit 10. Thank
13	I understand that the platelet	13	you
14	count can fluctuate up and down, but my	14	(Whereupon, Exhibit 10, Case report
15	concern in his history is that his	15	entitled, "Adverse Effects of Proton Pump
16	platelet count was trending downwards, and	16	Inhibitors on Platelet Count: A Case
17	there was really no other alternate	17	Report and Review of the Literature," by
18	explanation besides cirrhosis and portal	18	Subhajit Mukherjee, et al., was marked for
19	hypertension, which is, I think,	19	identification.)
20	substantiated by multiple other lines of	20	BY MR. VAUGHN:
21	evidence.	21	Q. Doctor, have you seen this case
22	BY MR. VAUGHN:	22	report before?
23	Q. After this date 11/4/2015, are you	23	A. I don't think so, not to my
24	aware of his platelets going back up ever?	24	recollection.
25	A. Let's see. I don't know if I	25	Q. Okay. And do you see here it was
	Page 255		Page 257
1	exhaustively listed all of his platelet counts.	1	published in 2018?
2	I I couldn't excuse me I couldn't tell	2	I just want
3	you concretely yes or no. I think I may have	3	A. Yes, I see that.
4	picked a couple other time points to look at.	4	Q. Okay. I just want to take you to
5	Q. Did you only list his only low	5	the third page where they note, "Based on the
6	platelet counts in your report?	6	findings from these case reports and from our
7	MS. ROSE: Object to the form.	7	observation, it appears that PPIs can cause
8	THE WITNESS: Well, clearly not	8	thrombocytopenia."
9	because we already reviewed some of the	9	Did I read that correctly?
10	the normal range platelet counts from	10	A. Yes. You read that correctly.
11	earlier in his medical history.	11	Q. Okay. And as you were forming your
12	BY MR. VAUGHN:	12	opinions in this case, were you aware that PPIs
13	Q. After the first one that was	13	could cause thrombocytopenia?
14	normal, once it started trending downwards, did	14	MS. ROSE: Object to the form.
15	you list any of them that were normal?	15	THE WITNESS: So you're showing me
16	MS. ROSE: Object to the form.	16	what appears to be a case series, which
17	THE WITNESS: I would have to	17	I I think I articulated previously are
18	review briefly here. I'll take a look.	18	not very strong sorry. It's a case
19	MR. VAUGHN: We can take a break	19	report, not a case series.
20	now, Nina.	20	This is based on this is one
21	MS. ROSE: Oh, sure. Do you want	21	case of a 35-year-old female who came in
22	to take the break right now?	22	with abdominal pain with a past history of
23	MR. VAUGHN: Yeah. Now works.	23	heartburn and treated with PPI.
24	THE VIDEOGRAPHER: Off the record,	24	It's very hard to make an inference
25	2:32.	25	about one from a case report or even a
			acout one from a case report of even a

	5. 46		5 00
1	Page 258	1	Page 260
	case series, for that matter, what is the	1	very specific reason that PPIs are
2	true causal association between something	2	oftentimes falsely associated with
3	like a PPI and an outcome.	3	sometimes very serious clinical end points
4	This is not robust evidence in my	4	that are later found to be totally
5	view, and I'll just say that as a	5	irrelevant and unsubstantiated.
6	gastroenterology, you know, I I	6	If I may just give a very quick
7	prescribe PPIs very frequently. Many of	7	example to drive this point home. There
8	my patients with MASLD and MASH are on	8	were some very big headlines media
9	PPIs. Probably the majority of them are	9	headlines that came out I don't know.
10	on PPIs, and I can't think of a single	10	It was quite a few years ago now that PPIs
11	case personally where low platelets are	11	cause heart attacks, and those were based
12	attributed to PPIs in this patient cohort.	12	on associational studies where patients,
13	But PPIs more generally are very	13	you know, presenting with chest
14	commonly falsely associated with different	14	discomfort, you know, who were then
15	medical end points because they're so	15	started on proton-pump inhibitors
16	commonly used for a variety of different	16	presuming that it was related to gastric
17	conditions.	17	reflux.
18	So, you know, I can't comment to	18	The the association is in those
19	the the details of all the different	19	studies were that PPIs were then
20	case reports that they may be referencing	20	associated with increased risk of having a
21	here to form some assessment of a a	21	heart attack shortly after a PPI was
22	case series, but they they report just	22	started.
23	a small number of case reports that	23	Very well-controlled studies that
24	demonstrate this.	24	subsequently came out that accounted for
25	But like I said, you know, case	25	confounders of coronary artery disease
	Page 259		Page 261
1	reports are not associational studies.	1	demonstrated that the chest discomfort was
2	They are not estimating they're not	2	not from the reflux. It was from heart
3	performing any analytical statistical	3	disease. And the patient's were had very
4	analysis to estimate what is the risk of	4	high risk of having an impending heart
5	low platelet counts with with PPI	5	attack, but PPIs were just started because
6	exposure.	6	some clinician thought, okay, maybe this
7	So it's really hard to translate	7	PPI will treat the chest discomfort. So
8	this to to Mr. Roberts and say with any	8	you get this false association between
	•	9	, ,
9	degree of certainty that PPIs were		PPIs and heart attacks that's not real.
10	would be related to his platelet count.	10	So I I highlight that because
11	Though in my view, it's almost certainly	11	there are lots of you'll find lots of
12	unrelated.	12	case reports and series alleging that PPIs
13	BY MR. VAUGHN:	13	are linked with all sorts of things.
14	Q. And you didn't do any research on	14	You know, this I'm not sure what
15	PPIs causing low platelet counts, correct?	15	was going on with this particular patient,
16	MS. ROSE: Object to the form.	16	you know, when she what symptoms she
17	THE WITNESS: So in the course of	17	was having and the PPI may have been
18	this particular case, no, I didn't explore	18	started for some generic reason when, in
19	any specific associations about PPIs and	19	fact, something else was going on that was
20	low platelet counts for the context of	20	driving the low platelets. But there's no
21	this case, but I am familiar broadly with	21	way to say without, you know, a high
22	a lot of the PPI-related liter	22	quality analytic study.
23	literature as pertaining to a wide variety	23	So I don't view this to be very
24	of clinical outcomes.	24	strong evidence. And again, you know, in

	Page 262		Page 264
1	PPIs, I would expect that there would be	1	limited sense. I think if somebody is
2	very, very strong evidence if this was a	2	dechallenged and rechallenged, you the issue
3	real causal association.	3	is that you would also know what other relevant
4	BY MR. VAUGHN:	4	factors may also be changing in a patient.
5		5	So, you know, if I'm trying to
	Q. Are you familiar with the term	Ι.	
6	de scratch that. Sorry.	6	look at this figure to understand just give
7	Are you familiar with the term	7	me a second to look at this Figure 1 to try to
8	"dechallenge"?	8	catch up where you're going with this.
9	A. Sorry. Dechallenge?	9	Yeah. So this patient, it looks
10	Q. Uh-huh.	10	like they're on a PPI. It is then
11	A. I I may be. When you you	11	discontinued. They are restarted on the PPI.
12	take someone off a medication, is that what	12	It is then discontinued.
13	you're referring to, when you stop a	13	So there's a there was, it looks
14	medication?	14	like two dechallenges, in this case report.
15	Q. Right?	15	Is that what you're referring to?
16	A. Yes, yes. I'm familiar with that	16	Q. Yeah. And you mentioned a
17		17	rechallenge.
18	Q. Can you explain what a dechallenge	18	What does that mean?
19	is?	19	What's a "rechallenge"?
20	A. Yeah. If I'm understanding what	20	A. Sorry. A rechallenge, what I mean
21	you're referring to correctly, you know,	21	there is if someone is given a medication
22	someone who is on the medication, and then you	22	again.
23	take them off the medication and observe.	23	Q. And the side effects happen again?
24	Is that what you're referring to?	24	MS. ROSE: Object to the form.
25	Q. It is what I'm referring to.	25	THE WITNESS: Sorry. The
	`	23	
1	Page 263 A. Okay.	1	Page 265 rechallenge just refers to reintroducing
2	Q. Is are dechallenges strong	2	whatever the exposure is.
3	evidence?	3	BY MR. VAUGHN:
4	MS. ROSE: Object to the form.	4	Q. And they're with the
5	THE WITNESS: Yeah. It really	5	rechallenge, though, are they looking to see if
	depends on the context in which it's being		
6		6	the side effect happens again when the exposure
7	used. I mean, I think if you, you know,	7	is presented again?
8	do dechallenge dechallenges in the	8	MS. ROSE: Object to the form.
9	setting of a very-well controlled study	9	THE WITNESS: Yeah. So again, in
10	with a sufficient sample size looking for	10	the setting of a case report, this is not
11	some particular outcome, then it may be	11	being done in an interventional way. You
12	relevant.	12	know, they're it's not like she was
13	But it entirely depends on the	13	part of a study where they were going to
14	<u> </u>	14	give her a PPI, observe her, then
15	•	15	dechallenge her, observe her, rechallenge
16	and, you know, what the rigor of the	16	her, observe her. That's not the point of
	arrangement of a most had a large in the atride is	17	this.
17	surrounding methodology in the study is.	l	It my understanding most of
	So it's hard to answer precisely,	18	
17	So it's hard to answer precisely,	18 19	the time in case reports, and I can read
17 18	So it's hard to answer precisely, but there are many other considerations	l .	
17 18 19 20	So it's hard to answer precisely, but there are many other considerations besides a dechallenge itself that, you	19 20	the time in case reports, and I can read this in more detail to confirm this, but
17 18 19 20 21	So it's hard to answer precisely, but there are many other considerations besides a dechallenge itself that, you know, might be relevant to know.	19 20 21	the time in case reports, and I can read this in more detail to confirm this, but the patient happened to have been given a
17 18 19 20 21 22	So it's hard to answer precisely, but there are many other considerations besides a dechallenge itself that, you know, might be relevant to know. BY MR. VAUGHN:	19 20 21 22	the time in case reports, and I can read this in more detail to confirm this, but the patient happened to have been given a PPI. It happened to have been stopped.
17 18 19 20 21	So it's hard to answer precisely, but there are many other considerations besides a dechallenge itself that, you know, might be relevant to know. BY MR. VAUGHN: Q. Does a dechallenge make a case	19 20 21	the time in case reports, and I can read this in more detail to confirm this, but the patient happened to have been given a

1	Page 266	1	Page 268
1	And it's an important distinction	1	I could I could tell you if I've seen it or
2	because it's not being done in an	2 3	not. Q. I don't know what the citation is
3	experimental setting. She's not being		
4	given this and taken off of it while	4	either.
5	controlling for myriad other factors that	5	A. Okay.
6 7	may or may not be relevant. So it's it's not so so	6	Q. I didn't know you were aware of a
1		0	retrospective study that looked into PPI use being associated with thrombocytopenia before
8 9	even using the term like "dechallenge" and	8	, ,
10	"rechallenge," I don't want to imply that this is being done in an interventional	10	you authored your expert report.
11	sense because I don't think that's what		MS. ROSE: Object to the form.
12		11	THE WITNESS: And yeah. I'd really
1	this is this case report is stating.	12	have to know what they're referring to.
13	BY MR. VAUGHN:	13	They don't seem to offer the citation, so
	Q. Are you familiar with the term "double dechallenge"?	14	I I can't really speak to the validity or even the presence of it if it's not
15 16	A. I don't know if I've used that term	15 16	referenced or cited.
			BY MR. VAUGHN:
17 18	previously, but I can infer that you're	17 18	
19	referring to someone who has been dechallenged twice.	19	Q. And you didn't do any searching for PPIs being linked to thrombocytopenia, correct?
20		20	MS. ROSE: Object to the form.
21	Q. Uh-huh. Does that provide stronger evidence of a causal link?	21	THE WITNESS: Yeah. Like I said,
22	MS. ROSE: Object to the form.	22	in the context of this specific case, I
23	THE WITNESS: Yeah. I think my	23	did not do any dedicated searches for PPI
24	response is similar, where if it's not	24	and thrombocytopenia for this.
25	done in a very controlled setting in the	25	But again, I have to emphasize that
23		23	-
1	Page 267 context of some sort of interventional	1	Page 269
$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$		1 2	I'm not really relying exclusively on the platelet count to make my determinations
3	study or very well-adjusted study that is,	3	of, you know, presence or absence of
4	you know, really designed appropriately to look for potential causal associations,	4	cirrhosis in Mr. Roberts' case. It's
5	then no. I mean, it doesn't it's	5	myriad factors that I'm using as a
6	not I I wouldn't be able to	6	composite to arrive at a conclusion.
7	translate that to a causal association.	7	BY MR. VAUGHN:
8	It you know, all this my same	8	Q. And you agree that Mr. Roberts'
9	previous points, I think, still apply.	9	platelet count dropped after he was started on
10	You're not controlling other aspects of	10	a PPI, correct?
11	the situation. I don't know what other	11	•
12	co-associated factors may have also	12	A. Hold on. Let me take a look at my report for a moment. Let's see.
13	changed, you know, at the time that a PPI	13	So I think the problem with the
14	may have been reintroduced, for instance.	14	assertion that I think you're you're
15	BY MR. VAUGHN:	15	implying was that Mr. Roberts is on a PPI for
16	Q. Okay. And the authors here note	16	quite some time. You know, if you're trying to
17	that thrombocytopenia attributed to use of PPIs	17	impute that or suggest that there's a
18	has been described in a few case reports and a	18	relationship between an exposure and an
19	retrospective study.	19	outcome, obviously the temporal association is
20	Are you aware of what retrospective	20	relevant.
21	study they're referencing here?	21	I would agree that if you start
22	A. I'd have to see what the citation	22	someone on a medication and you very quickly
23	is.	23	see some relevant change in their labs or or
24	Q. Okay.	24	symptoms, then you you dechallenge them and
25	A. If you could maybe show that to me,	25	you rechallenge them, and you see that there is
	James de la		, G, J 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2

	P 270		D 272
1	Page 270 a very close approximation, that is you	1	Page 272 But again, I think the this case
	know, that's more evidence than not. I still	l	report the degree of thrombocytopenia was
3	don't think it's a well-established causal	3	extremely notable. It dropped, you know, very
4	association, but that's not what we're	4	close to zero. You know, it nattered very low
5	observing in Mr. Roberts. Mr. Roberts was	5	on this this chart. That's not really the
6	diagnosed with GERD in 2011 and started on a	6	the pattern for Mr. Roberts. It was more of
7	PPI in 2011.	7	a gradual decline.
8	So, you know, this case report here	8	Q. And Mr. Roberts only had very mild
9	is basically showing that, you know, in this	9	thrombocytopenia, correct?
10	patient she was started on a PPI sorry.	10	MS. ROSE: Object to the form.
11	I'll look at the the time course again here.	11	THE WITNESS: I wouldn't I
12	And it's over the course of a	12	wouldn't say that. I'm just saying that
13	shorter window of time, you know, when when	13	the cadence and the pattern that's
14	this patient developed a low platelet count and	14	sergeant in this report that you're
15	in a much more severe thrombocytopenia than was	15	showing me is where someone goes from a
16	observed in Mr. Roberts, but these are really	16	very normal robust platelet count to
17	being studied over the course of less than a	17	practically zero. It's a very extreme
18	year.	18	oscillation in the platelet count.
19	Mr. Roberts had been exposed to a	19	Whereas, Mr. Roberts, if you were
20	PPI for, you know, four years, you know, four	20	to map out his platelet count, it seems to
21	years really prior to developing overt	21	be dropping gradually, trending downward
22	thrombocytopenia. So it's it's really not	22	gradually over time, which is very
23	plausibly linked in my view to being causal of	23	consistent and expected with the the
24	1 , 1 , 5	24	tempo of cirrhosis.
25	evidence of he had portal hypertension, which	25	
	Page 271		Page 273
1	fits directly with his low platelet count.	1	BY MR. VAUGHN:
2	So it's a much, much more likely	2	Q. What is a very normal platelet
3	explanation for what's going on with	3	count?
4	Mr. Roberts than what I think you might be	4	A. So a normal platelet count is over
5	suggesting.	5	150. When I say that I guess when I say
6	Q. Are you aware of any platelet		
7	C 2011 1 1 1 DDY	6	very normal, it's it's very close to the
'	counts from 2011 when he started the PPI to	7	the center of the normal range.
8	November 4th, 2015?	7 8	the center of the normal range. Q. And what is that?
9	November 4th, 2015? A. I don't think I noted those in	7 8 9	the center of the normal range. Q. And what is that? A. So, you know, a normal range is
9 10	November 4th, 2015? A. I don't think I noted those in my in my report. So I'm not sure. I can't	7 8 9 10	the center of the normal range. Q. And what is that? A. So, you know, a normal range is typically, you know, 150 to 400. So someone
9 10 11	November 4th, 2015? A. I don't think I noted those in my in my report. So I'm not sure. I can't confirm or deny if there are platelet counts	7 8 9 10 11	the center of the normal range. Q. And what is that? A. So, you know, a normal range is typically, you know, 150 to 400. So someone that's in, you know, the mid-200s is
9 10 11 12	November 4th, 2015? A. I don't think I noted those in my in my report. So I'm not sure. I can't confirm or deny if there are platelet counts checked in those windows.	7 8 9 10 11 12	the center of the normal range. Q. And what is that? A. So, you know, a normal range is typically, you know, 150 to 400. So someone that's in, you know, the mid-200s is that's that's a very normal platelet count.
9 10 11 12 13	November 4th, 2015? A. I don't think I noted those in my in my report. So I'm not sure. I can't confirm or deny if there are platelet counts checked in those windows. It looks like the most recently	7 8 9 10 11 12 13	the center of the normal range. Q. And what is that? A. So, you know, a normal range is typically, you know, 150 to 400. So someone that's in, you know, the mid-200s is that's that's a very normal platelet count. Q. Okay. So Mr. Roberts starting off
9 10 11 12 13 14	November 4th, 2015? A. I don't think I noted those in my in my report. So I'm not sure. I can't confirm or deny if there are platelet counts checked in those windows. It looks like the most recently available platelet count prior was the value	7 8 9 10 11 12 13 14	the center of the normal range. Q. And what is that? A. So, you know, a normal range is typically, you know, 150 to 400. So someone that's in, you know, the mid-200s is that's that's a very normal platelet count. Q. Okay. So Mr. Roberts starting off at 175 is starting off on the lower end of
9 10 11 12 13 14 15	November 4th, 2015? A. I don't think I noted those in my in my report. So I'm not sure. I can't confirm or deny if there are platelet counts checked in those windows. It looks like the most recently available platelet count prior was the value from 2009. From late 2009 it was it was	7 8 9 10 11 12 13 14 15	the center of the normal range. Q. And what is that? A. So, you know, a normal range is typically, you know, 150 to 400. So someone that's in, you know, the mid-200s is that's that's a very normal platelet count. Q. Okay. So Mr. Roberts starting off at 175 is starting off on the lower end of normal?
9 10 11 12 13 14 15 16	November 4th, 2015? A. I don't think I noted those in my in my report. So I'm not sure. I can't confirm or deny if there are platelet counts checked in those windows. It looks like the most recently available platelet count prior was the value from 2009. From late 2009 it was it was 174. I'm not certain if there's another one	7 8 9 10 11 12 13 14 15 16	the center of the normal range. Q. And what is that? A. So, you know, a normal range is typically, you know, 150 to 400. So someone that's in, you know, the mid-200s is that's that's a very normal platelet count. Q. Okay. So Mr. Roberts starting off at 175 is starting off on the lower end of normal? A. Well, I don't
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9 10 11 12 13 14 15 16 17 18 19 20 21 22	November 4th, 2015? A. I don't think I noted those in my in my report. So I'm not sure. I can't confirm or deny if there are platelet counts checked in those windows. It looks like the most recently available platelet count prior was the value from 2009. From late 2009 it was it was 174. I'm not certain if there's another one available from this record between 2011 and 2015. Q. And so we can't tell when his platelets dropped after starting the PPI, correct? A. Yeah. I think that's fair to say.	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	the center of the normal range. Q. And what is that? A. So, you know, a normal range is typically, you know, 150 to 400. So someone that's in, you know, the mid-200s is that's that's a very normal platelet count. Q. Okay. So Mr. Roberts starting off at 175 is starting off on the lower end of normal? A. Well, I don't MS. ROSE: Object to the form. THE WITNESS: Sorry. Yeah. I don't know what his unfortunately, his platelet counts are not, you know, recorded earlier in his adulthood. So I don't actually know

	Page 274		Page 276
1	records, unfortunately.	1	the time in my practice who develop
2	All I can see is where he is	2	cirrhosis.
3	starting out is in the normal range in his	3	BY MR. VAUGHN:
4	records. You know, 2009 I think is the	4	Q. And so because portal hypertension
5	first one that I I noted when it	5	is the most likely explanation for most
6	was 174. So he's normal there, but he's	6	patients, did you not feel it was necessary to
7	already on the lower end of the normal	7	do research into other causes of
8	range. I would acknowledge that.	8	thrombocytopenia specific to Mr. Roberts?
9	BY MR. VAUGHN:	9	MS. ROSE: Object to the form.
10	Q. And back to the study we were	10	THE WITNESS: No. I wouldn't say
11	looking at, this specific patient they note,	11	that. I you know, I I I'd be
12	"Thrombocytopenia immediately developed after	12	
1	· · ·	13	interested certainly to review, you know, in more detail relevant literature
13 14	initiation of PPI on two separation occasions and resolved after it's discontinuation."	14	
1			pertaining to proton-pump inhibitors and
15	Do you read that to be a double	15	thrombocytopenia to see what the strength
16	dechallenge with a rechallenge?	16	of the evidence. And I always reserve my
17	A. Yeah. I think, based on the	17	right right to revise any aspect of my
18	definition of double dechallenge that, you	18	opinion.
19	know, you gave me and we discussed, that's what	19	But what you're showing me is not
20	it sounds like, yeah. They took the patient	20	compelling evidence for the reasons that
21	off the medication on two occasions, and they	21	I've stated. It's a case report, and they
22	noted what the platelet counts were.	22	reference other other case reports to
23	Q. And so was one of your issues with	23	construct an idea of a case series, but
24	the PPI being associated with Mr. Roberts'	24	these are not controlled, you know,
25	thrombocytopenia is that gap the temporality	25	analytic studies to that are capable of
	Page 275		Page 277
1	gap of it starting in 2011 and him presenting	1	demonstrating, you know, statistical
2	with what you call thrombocytopenia in 2015?	2	associations between an exposure and an
3	MS. ROSE: Object to the form.	3	outcome. They're just case reports.
4	THE WITNESS: That's I mean, I '	4	So I don't view them to be strong
5	just highlighting that one issue because	5	evidence. You know, they're they're
6	the case report you're showing me shows	6	and interesting thing that may be the
7	very extreme changes over a short time	7	basis for for future research in an
8	period with this PPI exposure. And I	8	in an observational study or a trial
9	don't think we have any evidence of that	9	setting or whatever it might be. But I
10	in Mr. Roberts. You know, he never got	10	don't view that to be well-founded causal
11	his platelet count close to zero.	11	associations that are demonstrated to be
12	And, you know but moreover, I	12	relevant here.
13	think that again, I'm considering other	13	So I I rely on the corpus of
14	factors beyond the platelet count to try	14	medical literature that is very
15	to understand why it is that it's	15	well-established, you know, from a
16	gradually downtrending in his in his	16	cirrhosis standpoint that I think is
17	case.	17	relevant here that demonstrates that this
18	And, you know, everything I'm	18	is the expected trajectory of platelet
19	reviewing in his history, there's very	19	counts in patients with preexisting
20	strong evidence that he has had	20	chronic liver disease who develop
21	progressive fibrosis and cirrhosis and	21	cirrhosis and progress to developing
		22	portal hypertension.
22	then development of portal hypertension,	44	
22 23	which is the most likely explanation for	23	BY MR. VAUGHN:
22			

1 Is are diuretics a class of drugs that can cause thrombocytopenia? 3 A. I am not a hundred percent sure. 4 If its possible, I mean depending on the diuretics. There's a lot of different diuretics. There's a lot of different might be one that is associated with thorobocytopenia to a significant degree. 11 Q. And you didn't do any research in 12 your scratch that. 13 And you didn't do any research in 14 draftling your expert opinion to see if 15 diuretics were a cause of thrombocytopenia, 16 correct? 16 diuretics were a cause of thrombocytopenia, 16 correct? 17 A. I didn't do any specific research 19 the association between diuretics and 20 thrombocytopenia, but, you know, I'd say that 21 in the course of my practice, you know, we use 22 diuretics very frequently in patients with 21 in the course of my practice, you know, we use 22 diuretics were frequently in patients with 21 where it's posited as an explanation for extreme thrombocytopenia in some patients, but 1 don't know it to be a strong association in 7 my clinical practice. 1 Page 27 1 There you know, I don't discount 2 that there might be some exceptional cases 3 where there might be associations or where 4 where it's posited as an explanation for extreme thrombocytopenia in some patients, but 1 don't know it to be a strong association in 7 my clinical practice. 2 Q. Okay. And did you review 9 Mr. Roberts' pharmacy records to see if any 10 medications were changed right before his 11 platelets dropped for the first time? 12 A. Yeah. I mean, I did review you 13 know, every time he saw a clinician, I did look through his medical record to to ruy to keep 15 track of big changes; but I couldn't 19 might before his 19 platelets dropped for the first time? 10 might before his 19 platelets dropped for the first time? 10 might before his 19 platelets dropped for the first time? 11 A. No, I did not specifically look at 11 A. No, I did not specifically look at 11 A. No, I did not specifically look at 11 A. No, I did not specifically look at				
drugs that can cause thrombocytopenia? A. I am not a hundred percent sure. It's possible, I mean depending on the diuretics. There's a lot of different diuretics that are used. So I don't immediately know — I don't do any research in the drafting your expert opinion to see if duretics were a cause of thrombocytopenia, in duretics were a cause of thrombocytopenia, in the thrombocytopenia by the association between diuretics and 20 thrombocytopenia; but, you know, I don't discount 2 them all the time, and it's certainly not 25 something that we see in routine practice. 1 There — you know, I don't discount 2 that there might be some exceptional cases where there might be association for 5 extreme thrombocytopenia in some patients, but 1 I don't know it to be a strong association in 7 my clinical practice. 2 Q. Okay. And did you review 9 Mr. Roberts' pharmacy records to see if any 10 medications were changed right before his 1 platelets dropped for the first time? 12 A. Yeah. Imean, I did review — you 13 know, every time he saw a clinician, I did look 14 through his medical record to — to try to keep 15 track of big changes; but I couldn't 19 20 — 2009 or antecedent to, you know, his platelet count in 19 20 — 2009 or antecedent to, you know, his platelet count in 19 20 — 2009 or antecedent to, you know, his platelet count in 19 20 — 2009 or antecedent to, you know, his platelet count in 19 20 — 2009 or antecedent to, you know, his platelet count in 19 20 — 2009 or antecedent to 2015 off the top 20 in the pharmacy records as exhibit, I 24 believe, 11.	1	Page 278	1	Page 280
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11 Q. And you didn't do any research in 12 your scratch that. 12 that. That's the first time that he had 13 thrombos thrombocytopenia by my definition, 14 yes. 15 diuretics were a cause of thrombocytopenia, 16 correct? 17 A. I didn't do any specific research 18 for this expert report specifically looking at 19 the association between diuretics and 20 thrombocytopenia; but, you know, I'd say that 21 in the course of my practice, you know, we use 22 diuretics very frequently in patients with 21 liver disease. And so I count encounter 24 them all the time, and it's certainly not 25 something that we see in routine practice. Page 279 1 There you know, I'd on't discount 2 that there might be associations or where where it's posited as an explanation for 5 extreme thrombocytopenia in some patients, but 6 I don't know it to be a strong association in my clinical practice. 8 Q. Okay. And did you review 9 Mr. Roberts' pharmacy records to see if any medications were changed right before his 11 platelets dropped for the first time? 12 A. Yeah. 15 Q. I'm on page 2 here. All right. So on 7/27/2015, we see he's taking Valsartan, 320 milligrams, correct? 18 A. Yes. I see that. 19 Q. Okay. And then on 10/8/2015, do Quo see where they transitioned him now to Valsartan HCTZ! 2 A. Yeah. 22 A. Yeah. 22 A. Yeah. 23 Q. Okay. And so this would have been approximately two to three weeks before these labs were drawn, correct? 1 A. That's hydrochlorothiazide, Walsartan, 320 milligrams, correct? 19 Q. Okay. And then on 10/8/2015, do Quo see where they transitioned him now to Valsartan, 320 milligrams, correct? 22 A. Yeah. 23 Q. Okay. And so this would have been approximately two to three weeks before these labs were drawn, correct? 24 A. That's hydrochlorothiazide, Whithis is a diuretic medication. Q. Okay. Did you do any research into hydrochlorothiazid	1	-		-
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19 the association between diuretics and 20 thrombocytopenia; but, you know, I'd say that 21 in the course of my practice, you know, we use 22 diuretics very frequently in patients with 23 liver disease. And so I count encounter 24 them all the time, and it's certainly not 25 something that we see in routine practice. Page 279 1 There you know, I don't discount 2 that there might be some exceptional cases 3 where there might be associations or where 4 where it's posited as an explanation for 5 extreme thrombocytopenia in some patients, but 6 I don't know it to be a strong association in 7 my clinical practice. 8 Q. Okay. And did you review 9 Mr. Roberts' pharmacy records to see if any 10 medications were changed right before his 11 platelets dropped for the first time? 12 A. Yeah. I mean, I did review you 13 know, every time he saw a clinician, I did look 14 through his medical record to to try to keep 15 track of big changes; but I couldn't 16 immediately tell you off the top of my head 17 what specific changes might have been made antecedent to, you know, his platelet count in 18 antecedent to, you know, his platelet count in 19 Q. Okay. And then on 10/8/2015, do you see where they transitioned him now to Valsartan HCTZ? A. Yeah. 22 A. Yeah. 23 Q. Okay. And so this would have been approximately two to three weeks before these labs were drawn, correct? Page 279 A. That's hydro stand for in Valsartan? 4 A. That's hydro 5 extreme thrombocytopenia in some patients, but 6 A. It's it's hydrochlorothiazide, which is a diuretic medication. 9 Okay. Did you do any research into hydrochlorothiazide and thrombocytopenia when coming to your expert opinion? A. No, I did not specifically look at hat association. MR. VAUGHN: All right. Kathryn, can we do the 1986 study on hydrochlorothiazide-induced thrombocytopenia. MS. AVILA: Yes. And that's Exhibit 12. (Whereupon, Exhibit 12, Study Entitled, "Hydrochlorothiazide-Induced Thrombocytopenic Purpura," by Kingsley C. Okafor, et al., was ma				_
20 thrombocytopenia; but, you know, I'd say that 21 in the course of my practice, you know, we use 22 diuretics very frequently in patients with 23 liver disease. And so I count encounter 24 them all the time, and it's certainly not 25 something that we see in routine practice. Page 279 1 There you know, I don't discount 2 that there might be some exceptional cases 3 where there might be associations or where 4 where it's posited as an explanation for 5 extreme thrombocytopenia in some patients, but 6 I don't know it to be a strong association in 7 my clinical practice. 8 Q. Okay. And did you review 9 Mr. Roberts' pharmacy records to see if any 10 medications were changed right before his 11 platelets dropped for the first time? 12 A. Yeah. I mean, I did review you 13 know, every time he saw a clinician, I did look 14 through his medical record to to try to keep 15 track of big changes; but I couldn't 16 immediately tell you off the top of my head 17 what specific changes might have been made 18 antecedent to, you know, his platelet count in 19 20 2009 or antecedent to 2015 off the top 20 of my head. 21 Q. Okay. 22 MR. VAUGHN: Kathryn, can you drop 23 in the pharmacy records as exhibit, I 24 believe, 11. 25 A. Yeah. 26 A. Yeah. 27 A. Yeah. 28 A. Yeah. 29 Okay. And so this would have been 29 da. Yeah. 20 Okay. And what does the "HCTZ" 20 Okay. And what does the "HCTZ" 21 A. Yeah in Walsartan? 22 A. That's hydrochlorothiazide, 23 where thery transitioned him now to 24 A. Yeah. 24 A. Yeah. 25 In Yeah. 26 A. Yeah. 27 A. Yeah. 28 A. Yeah. I would agree with that. 29 Okay. And what does the "HCTZ" 29 Okay. Did you do any research into hydrochlorothiazide, 20 Okay. Did you do any research into hydrochlorothiazide and thrombocytopenia when coming to your expert opinion? 29 A. No, I did not specifically look at that association. 30 Okay. Did you do any research into hydrochlorothiazide induced thrombocytopenia. 31 MR. VAUGHN: All right. Kathryn, 32 Can we do the 1986 study on hydrochlorothiazide-indu	1			
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18 antecedent to, you know, his platelet count in 19 20 2009 or antecedent to 2015 off the top 20 of my head. 21 Q. Okay. 22 MR. VAUGHN: Kathryn, can you drop 23 in the pharmacy records as exhibit, I 24 believe, 11. 18 Exhibit 12. 19 (Whereupon, Exhibit 12, Study 20 Entitled, "Hydrochlorothiazide-Induced 21 Thrombocytopenic Purpura," by Kingsley C. 22 Okafor, et al., was marked for 23 identification.) 24 BY MR. VAUGHN:	16			* *
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23 in the pharmacy records as exhibit, I 24 believe, 11. 23 identification.) 24 BY MR. VAUGHN:	1	= •		
24 believe, 11. 24 BY MR. VAUGHN:	1			
	1		23	·
25 O Here we go 1986	1	believe, 11.		
23 Q. Here we go. 1760	25		25	Q. Here we go. 1986

	Page 282		Page 284
	Hydrochlorothiazide-induced what is what	1	oral diuretics had platelet counts less than
2	is what is this word?	2	100,000; is that correct?
3	Thrombocytopenic purpura, is that	3	MS. ROSE: Object to the form.
4	how you say it?	4	THE WITNESS: I mean, I agree
5	A. Yeah. Thrombocytopenic purpura.	5	that's what the sentence says. That's
6	Q. What does that mean?	6	what the yeah. You read it correctly.
7	A. Well, I have to say in 1986, this	7	BY MR. VAUGHN:
8	is quite a long time ago; and sometimes these	8	Q. And then it talks about when there
9	terms may have been used differently in that	9	is thrombocytopenia due to a thiazide diuretic,
10	era to be quite frank.	10	it's usually a gradual onset, mild rather than
11	The purpura generally refers to a	11	severe, and the decrease in platelet count
12	bruising that you might see on the skin related	12	occurs after several days of therapy, correct?
13	to very, very low platelet counts. You know,	13	A. Yes.
14	because platelets are important to, you know,	14	Q. And would you agree that several
15	to help with stopping bleeding. They're	15	days after Mr. Roberts was started on HCTZ, he
16	important for forming clots.	16	had a mild drop in his platelet count?
17	And so if you have extremely low	17	MS. ROSE: Object to the form.
18	platelet counts, you can sometimes she some of	18	THE WITNESS: Yeah. So based on
19	this spontaneous bruising. That that's how	19	the medication logs you showed me for the
20	it's commonly used currently. I'm not sure	20	timing of when the HCTZ was added to his
21	back in 1986 if that might have had a slightly	21	Valsartan, yeah. His platelet count was a
22	different connotation.	22	little bit lower on the subsequent check.
23	Q. Okay. And so back in 1986, they	23	BY MR. VAUGHN:
24	identified that the drug, which is	24	Q. And again, a dechallenge would be
25	hydrochlorothiazide, was discontinued. Two	25	if they then took him off of it and his
	Page 283		Page 285
1	weeks later the patient's symptoms resolved	1	platelets went back up, correct?
2	completely, and his platelet count returned to	2	A. I mean, the dechallenge portion of
3	normal.	3	that just refers to stopping the medication.
4	That's again describing a	4	Q. And then you looked to see if it
5	dechallenge, correct?	5	stops the side effect, correct?
6	MS. ROSE: Object to the form.	6	A. Sure. Yeah.
7	THE WITNESS: Let me take a look at	7	So you take someone off the
8	that.	8	medication, and then you observe them. I think
9	So the drug was discontinued. Two	9	that's an okay definition of a dechallenge
10	weeks later the platelet count was	10	here.
11	returned to normal. Let's see.	11	Q. And that's pretty good evidence of
12	Yeah. I guess yep. True. They	12	a causal link, correct?
13	took him off the medication, which if you	13	MS. ROSE: Object to the form.
14	want to define that as a dechallenge, then	14	THE WITNESS: Yeah. I think the
15	that appears to be what they did, yes.	15	same caveats I applied to the previous
	that appears to be what they did, yes.		11 1
16	BY MR. VAUGHN:	16	case report I would apply here. But
16 17	BY MR. VAUGHN:		case report I would apply here. But again, this is a case report, and this one
1	BY MR. VAUGHN: Q. And then they start talking about	17	again, this is a case report, and this one
17 18	BY MR. VAUGHN: Q. And then they start talking about thiazide diuretics.	17 18	again, this is a case report, and this one in particular is is from quite some
17 18 19	BY MR. VAUGHN: Q. And then they start talking about thiazide diuretics. HCTZ would qualify as a thiazide	17 18 19	again, this is a case report, and this one in particular is is from quite some time ago, from, you know, almost 40 years
17 18 19 20	BY MR. VAUGHN: Q. And then they start talking about thiazide diuretics. HCTZ would qualify as a thiazide diuretic, correct?	17 18 19 20	again, this is a case report, and this one in particular is is from quite some time ago, from, you know, almost 40 years ago.
17 18 19 20 21	BY MR. VAUGHN: Q. And then they start talking about thiazide diuretics. HCTZ would qualify as a thiazide diuretic, correct? A. Yes.	17 18 19 20 21	again, this is a case report, and this one in particular is is from quite some time ago, from, you know, almost 40 years ago. And it's very difficult to know the
17 18 19 20 21 22	BY MR. VAUGHN: Q. And then they start talking about thiazide diuretics. HCTZ would qualify as a thiazide diuretic, correct? A. Yes. Q. And it says, "Thiazide diuretics	17 18 19 20 21 22	again, this is a case report, and this one in particular is is from quite some time ago, from, you know, almost 40 years ago. And it's very difficult to know the complete clinical circumstances of of
17 18 19 20 21 22 23	BY MR. VAUGHN: Q. And then they start talking about thiazide diuretics. HCTZ would qualify as a thiazide diuretic, correct? A. Yes. Q. And it says, "Thiazide diuretics have been shown to induce thrombocytopenic	17 18 19 20 21 22 23	again, this is a case report, and this one in particular is is from quite some time ago, from, you know, almost 40 years ago. And it's very difficult to know the complete clinical circumstances of of the patient in terms of what else might
17 18 19 20 21 22	BY MR. VAUGHN: Q. And then they start talking about thiazide diuretics. HCTZ would qualify as a thiazide diuretic, correct? A. Yes. Q. And it says, "Thiazide diuretics	17 18 19 20 21 22	again, this is a case report, and this one in particular is is from quite some time ago, from, you know, almost 40 years ago. And it's very difficult to know the complete clinical circumstances of of

	Page 296		Page 288
1	Page 286 Like, it's it's very difficult to know	1	series. So the ones that you've shown me,
2	based on an N of one, one patient. You	2	these case reports, I don't find them
3	can't really use that to make inferences	3	compelling; and I would never extrapolate
4	more broadly about causal links. So	4	to say that they were the cause of
5	BY MR. VAUGHN:	5	Mr. Roberts' declining platelet count,
6		6	especially in light of the very, very
7	Q. Did you sorry.A. It's all right. Go ahead.	7	well-established scientific and medical
8	<u> </u>	8	
	Q. Do you see here, even though this		basis for platelet counts declining in the
9	is a 40-year-old study, they are citing to	9	setting of cirrhosis and portal
10	other studies that have already been done where	10	hypertension, which we know is present in
11	26 to 71 percent of patients have a decrease in	11	him.
12	their platelet count when they're on thiazide	12	So sometimes you can look at this
13	diuretics, correct?	13	almost as a weight weight of
14	MS. ROSE: Object to the form.	14	probabilities. You know, we try to
15	THE WITNESS: I would have to	15	determine what's most likely when we look
16	review those studies. I mean, I'm not	16	at a patient.
17	familiar, you know, with Kutti and	17	I have a preponderance of of
18	Weinfield's study.	18	reasons to suggest that platelet count is
19	But if I just focused on what	19	declining in Mr. Roberts because of his
20	you're saying, they say that 26 percent of	20	cirrhosis and portal hypertension. That
21	71 patients receiving oral diuretics had	21	is further substantiated the deeper you go
22	platelet counts less than 100,000.	22	into the record. You know, the platelet
23	They're actually not discussing trends	23	count keeps going down as as he
24	there. They're just saying 26 percent of	24	progresses toward decompensated cirrhosis
25	71 had a platelet count of less than 100.	25	in terms of a trend. It trends further
	Page 287		Page 289
1	The reason why I think it's so	1	downward.
2	dangerous to extrapolate from, you know,	2	So I have lots of data points in my
3	from very limited case reports and even	3	mind that that support that balanced
4	case series is why were those patients	4	against these isolated case reports where
5	started on diuretics?	5	this has not been systematically studied.
6	Were they started on diuretics	6	I have no idea what the potential
7	because they had evolving liver disease	7	confounders are. This is a very brief
8	and cirrhosis?	8	case report. This is not even really a
9	Fluid overload is a very common	9	full page before they begin to site some
10	symptom of advanced you know, of	10	references. It's extremely terse.
11	decompensated cirrhosis, and we start	11	So so yeah. And so if I were to
12	patients on diuretics for that purpose.	12	weigh the probabilities, you know,
13	Or they may develop edema in the lower	13	cirrhosis and portal hypertension is
14	extremities, and we start patients on	14	extremely likely. HCTZ, which we use all
15	diuretics.	15	the time all the time in medicine I
16	So unless you are controlling for	16	have so many patients who take HCTZ where
17	factors like this, you can't say that, you	17	we don't observe this. That is very, very
18	know, the other comorbid factors are	18	low in terms of probability of explaining
19	explaining why the platelet count is low.	19	why his platelet count is declining in my
20	You can't attribute it to the	20	view.
21	hydrochlorothiazide without very detailed	21	BY MR. VAUGHN:
22	and careful study of potential confounding	22	Q. So when you came to your opinions
23	factors.	23	in this case, you didn't consider the thiazide
24		24	diuretic or the PPI as a cause of his
24 25	So I always hesitate to to extrapolate from case reports and case	25	thrombocytopenia, correct?
	EXTRADORATE TROUT CASE REDORTS AND CASE	L Z.)	un omboeviobema, correct?

	Page 290		Page 292
1	MS. ROSE: Object to the form.	1	MR. VAUGHN: Can we make that
2	THE WITNESS: I looked at his	2	exhibit, I think, 13, Kathryn, the
3	medical list. I was aware that he was on	3	10/27/2016.
4	the PPI. I was aware that he was exposed	4	MS. AVILA: Give me one second. I
5	to hydrochlorothiazide.	5	lost it.
6	In my clinical experience, you	6	MR. VAUGHN: You're fine. And if
7	know, with these medications that I	7	you need me to drop it to you, let me
8	prescribe personally to many patients,	8	know.
9	that I manage patients who are frequently	9	MS. AVILA: Here it is.
10	on these medications, these are not	10	Exhibit 13.
11	typical side effects that we observe in	11	
12	· ·	12	(Whereupon, Exhibit 13, Medical Record, Bates labeled Restricted
13	clinical practice.	13	Confidential Information
14	Again, I'm not discounting the	14	GRobertsJr-AMG-000040, was marked for
15	possibility that a very unusual case could		identification.)
16	occur where someone does have, you know,	15	,
17	low platelets attributable to these	16 17	THE WITNESS: Okay. I think I have
18	things; but it's very, very unlikely and	18	it. BY MR. VAUGHN:
19	not something that we see in routine	_	
1	clinical practice. BY MR. VAUGHN:	19	Q. What was that?
20		20	A. I have it. Sorry.
21	Q. I am going back to your expert	21	Q. Okay. All right.
22 23	report. I'm on page 8.	22	So this is 10/27/2016, and this is
	A. Okay. All right. Page 8.	23	Dr. Sanders is saying, "His platelets are low,
24	Okay. I'm there.	24	and I'm not sure why," correct?
25	Q. On this 4/19/2016 CT scan, you note	25	A. Yes. And I remember this. I think
1	Page 291	1	Page 293
	that the radiologist says, "Although		I quoted this, a lot of this section
$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	nonspecific, the findings above may be evidence	2	specifically because he specifically then says,
3	of liver cirrhosis."	3	"He is not on any medications that could be
4	What does that mean, "nonspecific"?	4	causing this."
5	A. So, you know, I'd be speaking on	5	And in looking back, this was not a
6	behalf of the radiologists. So I don't	6	problem during his last CBC.
7	necessarily know what that particular	7	Q. So this is a new prob this is a
8	radiologist may have meant by that.	8	new onset problem as of 10/27/2016, correct?
9	But in my experience reading	9	MS. ROSE: Objection.
	radiology reports and talking to radiologists,	10	THE WITNESS: Well, you know, as
11	they usually mean this to be that there	11	I in my view, it's not that's the
12	there might be some uncertainty in their view	12	first time that Dr. Sanders is
13	that there could be cirrhosis.	13	specifically flagging this.
14 15	Q. And then you note 9/19/2016 was	14 15	But as we've already stated, you
1 17		רו	know, he had a prior lab in November 2015
	when Mr. Roberts was first exposed to		=
16	NDMA-contaminated Valsartan, correct?	16	when he had an abnormally low platelet
16 17	NDMA-contaminated Valsartan, correct? A. Yes.	16 17	when he had an abnormally low platelet count in my view.
16 17 18	NDMA-contaminated Valsartan, correct? A. Yes. Q. Okay. And then 10/17/2016 is the	16 17 18	when he had an abnormally low platelet count in my view. BY MR. VAUGHN:
16 17 18 19	NDMA-contaminated Valsartan, correct? A. Yes. Q. Okay. And then 10/17/2016 is the first time his doctors actually diagnosed his	16 17 18 19	when he had an abnormally low platelet count in my view. BY MR. VAUGHN: Q. But his treating physicians didn't
16 17 18 19 20	NDMA-contaminated Valsartan, correct? A. Yes. Q. Okay. And then 10/17/2016 is the first time his doctors actually diagnosed his thrombocytopenia, correct?	16 17 18 19 20	when he had an abnormally low platelet count in my view. BY MR. VAUGHN: Q. But his treating physicians didn't look at it as abnormally low, correct?
16 17 18 19 20 21	NDMA-contaminated Valsartan, correct? A. Yes. Q. Okay. And then 10/17/2016 is the first time his doctors actually diagnosed his thrombocytopenia, correct? A. Yeah. That's that's my first	16 17 18 19 20 21	when he had an abnormally low platelet count in my view. BY MR. VAUGHN: Q. But his treating physicians didn't look at it as abnormally low, correct? A. You know, I don't know. I can't
16 17 18 19 20 21 22	NDMA-contaminated Valsartan, correct? A. Yes. Q. Okay. And then 10/17/2016 is the first time his doctors actually diagnosed his thrombocytopenia, correct? A. Yeah. That's that's my first time I recall seeing a physician specifically	16 17 18 19 20 21 22	when he had an abnormally low platelet count in my view. BY MR. VAUGHN: Q. But his treating physicians didn't look at it as abnormally low, correct? A. You know, I don't know. I can't I can't speak on behalf of the physician. This
16 17 18 19 20 21 22 23	NDMA-contaminated Valsartan, correct? A. Yes. Q. Okay. And then 10/17/2016 is the first time his doctors actually diagnosed his thrombocytopenia, correct? A. Yeah. That's that's my first time I recall seeing a physician specifically mention the issue in in their clinical	16 17 18 19 20 21 22 23	when he had an abnormally low platelet count in my view. BY MR. VAUGHN: Q. But his treating physicians didn't look at it as abnormally low, correct? A. You know, I don't know. I can't I can't speak on behalf of the physician. This is the first time that his primary care doctor
16 17 18 19 20 21 22	NDMA-contaminated Valsartan, correct? A. Yes. Q. Okay. And then 10/17/2016 is the first time his doctors actually diagnosed his thrombocytopenia, correct? A. Yeah. That's that's my first time I recall seeing a physician specifically	16 17 18 19 20 21 22	when he had an abnormally low platelet count in my view. BY MR. VAUGHN: Q. But his treating physicians didn't look at it as abnormally low, correct? A. You know, I don't know. I can't I can't speak on behalf of the physician. This

	Dog 204		Page 206
1	Page 294 document something, I can't speak to that.	1	Page 296 really no other identifiable condition
2	Q. And just because the doctor's not	2	that would be known to cause low platelets
3	any medications that could be causing it, that	3	and then seemingly out of nowhere had a
4	doesn't mean the doctor actually did research	4	low platelet count without any other
5	into PPIs of HCTZ to see if it could be cause,	5	alternative expla explanation, that's
6	correct?	6	a scenario where you would very deeply
7		7	scrutinize a medication list to try to
	A. I mean, I can't really speak to what Dr. Sanders may or may not have done.		·
8 9	What I can say is it's clear that he's thought	8 9	understand what is going on. But that's that's simply not the
1	· · · · · · · · · · · · · · · · · · ·	l	± *
10	about medications here as being a potential	10	case for Mr. Roberts. He has very obvious
11	cause, and he's documented that specifically.	11	explanations for why his platelet count is
12	So I would assume that he looked through the	12	low in my view. And so you know, so
13	relevant medications that Mr. Roberts was on to	13	I'm attending to the things that I think
14	make that determination.	14	are most relevant in this case.
15	Q. Because in clinical practice,	15	BY MR. VAUGHN:
16	that's what you should do, right?	16	Q. And so is that why you did not need
17	You should look through all the	17	to deeply scrutinize his medication list?
18	medications and see if one of them were the	18	MS. ROSE: Object to the form.
19	cause?	19	THE WITNESS: Again, I'm not saying
20	MS. ROSE: Object to the form.	20	I didn't deeply scrutinize the medication
21	THE WITNESS: Yeah. I think in	21	list. As I stated previously, I reviewed
22	clinical practice, again, you should	22	his medications that he was on at that
23	you should think about the entire patient	23	time. I reviewed the medications that he
24	context and try to interpret a patient's	24	had been on at various points during his
25	labs and findings in the entire context.	25	medical history.
	Page 295		Page 297
1	So that in some cases may may involve	1	But in the context of of
2	looking at the medications with a lot of	2	Mr. Roberts' comorbid medical conditions,
2 3	looking at the medications with a lot of scrutiny.	2 3	Mr. Roberts' comorbid medical conditions, imaging, other lab findings, FIB-4, I had
2 3 4	looking at the medications with a lot of scrutiny. In other cases, to be quite frank,	2 3 4	Mr. Roberts' comorbid medical conditions, imaging, other lab findings, FIB-4, I had a very clear interpretation and
2 3 4 5	looking at the medications with a lot of scrutiny. In other cases, to be quite frank, if a patient has a very obvious reason to	2 3 4 5	Mr. Roberts' comorbid medical conditions, imaging, other lab findings, FIB-4, I had a very clear interpretation and understanding for why the platelet count
2 3 4 5 6	looking at the medications with a lot of scrutiny. In other cases, to be quite frank, if a patient has a very obvious reason to have a finding, you may need to spend less	2 3 4 5 6	Mr. Roberts' comorbid medical conditions, imaging, other lab findings, FIB-4, I had a very clear interpretation and understanding for why the platelet count would be declining; and that was
2 3 4 5 6 7	looking at the medications with a lot of scrutiny. In other cases, to be quite frank, if a patient has a very obvious reason to have a finding, you may need to spend less time scrutinizing a very unlikely cause	2 3 4 5 6 7	Mr. Roberts' comorbid medical conditions, imaging, other lab findings, FIB-4, I had a very clear interpretation and understanding for why the platelet count would be declining; and that was substantiated on his imaging that he had
2 3 4 5 6 7 8	looking at the medications with a lot of scrutiny. In other cases, to be quite frank, if a patient has a very obvious reason to have a finding, you may need to spend less time scrutinizing a very unlikely cause and put more of your emphasis on managing	2 3 4 5 6 7 8	Mr. Roberts' comorbid medical conditions, imaging, other lab findings, FIB-4, I had a very clear interpretation and understanding for why the platelet count would be declining; and that was substantiated on his imaging that he had shortly after the low platelet count.
2 3 4 5 6 7 8 9	looking at the medications with a lot of scrutiny. In other cases, to be quite frank, if a patient has a very obvious reason to have a finding, you may need to spend less time scrutinizing a very unlikely cause and put more of your emphasis on managing and evaluating and treating what's right	2 3 4 5 6 7 8 9	Mr. Roberts' comorbid medical conditions, imaging, other lab findings, FIB-4, I had a very clear interpretation and understanding for why the platelet count would be declining; and that was substantiated on his imaging that he had shortly after the low platelet count. So in my mind, there really wasn't
2 3 4 5 6 7 8 9 10	looking at the medications with a lot of scrutiny. In other cases, to be quite frank, if a patient has a very obvious reason to have a finding, you may need to spend less time scrutinizing a very unlikely cause and put more of your emphasis on managing and evaluating and treating what's right in front of you.	2 3 4 5 6 7 8 9	Mr. Roberts' comorbid medical conditions, imaging, other lab findings, FIB-4, I had a very clear interpretation and understanding for why the platelet count would be declining; and that was substantiated on his imaging that he had shortly after the low platelet count. So in my mind, there really wasn't much uncertainty as to why his platelet
2 3 4 5 6 7 8 9 10	looking at the medications with a lot of scrutiny. In other cases, to be quite frank, if a patient has a very obvious reason to have a finding, you may need to spend less time scrutinizing a very unlikely cause and put more of your emphasis on managing and evaluating and treating what's right in front of you. So that that's an important	2 3 4 5 6 7 8 9 10 11	Mr. Roberts' comorbid medical conditions, imaging, other lab findings, FIB-4, I had a very clear interpretation and understanding for why the platelet count would be declining; and that was substantiated on his imaging that he had shortly after the low platelet count. So in my mind, there really wasn't much uncertainty as to why his platelet count would behave in this way, trending
2 3 4 5 6 7 8 9 10 11 12	looking at the medications with a lot of scrutiny. In other cases, to be quite frank, if a patient has a very obvious reason to have a finding, you may need to spend less time scrutinizing a very unlikely cause and put more of your emphasis on managing and evaluating and treating what's right in front of you. So that that's an important clinical principle as well. You know,	2 3 4 5 6 7 8 9 10 11 12	Mr. Roberts' comorbid medical conditions, imaging, other lab findings, FIB-4, I had a very clear interpretation and understanding for why the platelet count would be declining; and that was substantiated on his imaging that he had shortly after the low platelet count. So in my mind, there really wasn't much uncertainty as to why his platelet count would behave in this way, trending downwards.
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	2.00		D 000
1	Page 298 As as we've talked about	1	Page 300
			A. Yeah. So the the physical exam
2	previously, you know, since he was a teenager, he had abnormal transaminases.	2	for detecting an enlarged spleen is extremely
3		3	unreliable. It's a very difficult technique
4	You know, the definition of chronic	4	that requires, honestly, a lot of experience
5	liver disease is having transaminases, AST, and	5	and and dedicated experience to identify an
6	ALT that are abnormal for at least six months	6	enlarged spleen reliably on exam.
7	that are, you know, plausibly attributable to	7	Cross-sectional imaging is vastly
8	some chronic inflammatory process.	8	superior to the physical exam for identifying
9	Mr. Roberts very clearly met those	9	an enlarged spleen because you can see the
10	criteria for a long time prior to 2016, likely	10	spleen directly and measure the spleen
11	since he was a teenager.	11	directly.
12	Q. As of 10/27/2016, Mr. Roberts had	12	So it's there's really no
13	not been diagnosed with cirrhosis, correct?	13	question on a CT scan if it's if it's
14	A. So as of 10/27/2016 so again,	14	present or not, you know, assuming a qualified
15	I'll not that, you know, his CT scan imaging	15	radiologist reviews it.
16	the possibility of cirrhosis was raised on, you	16	Q. What is your basis that he is
17	know, April 19th, 2016.	17	saying this based off of a physical exam and
18	You know, I would agree that he	18	not the imaging, or are you speculating?
19	it doesn't appear that he was given a formal	19	MS. ROSE: Object to the form.
20	diagnosis of cirrhosis by his treating	20	THE WITNESS: So that's that's a
21	physicians until a bit later in his medical	21	good point. I mean, he may have looked
22		22	I can't rule out the possibility that he
23	is that he had already had cirrhosis at this	23	may have looked at the CT scan. I suspect
24	point.	24	he if he did review the imaging, the
25	Q. As of 10/27/2016, Mr. Roberts had	25	CT scan, he probably reviewed the
	Page 299		Page 301
1	not been diagnosed with portal portal	1	radiology report, where that particular
2	hypertension, correct?	2	radiologist did not comment on the spleen
3	A. He had not been given a formal	3	being enlarged.
4	diagnosis of portal hypertension at that time	4	So yes. I mean, I I I'd have
5	point; though, again, in my review of his	5	to see again his physical exam from that
6	, 1 31	6	visit to see if he maybe he mentions
7	very, very clearly present as indicated, you	7	it. I'm not sure. I'm trying to see.
8	know, really confirmed on his CT scan from	8	Yeah. I I guess we just have
9	April of 2016.	9	this one page. I think it would have been
10	Q. And Mr. Sanders, his treating	10	on a page above this one, perhaps, where
11	physician, can't figure out why his platelets	11	in his documentation of the physical exam,
12	are low to 10/27/2016, correct?	12	if he specifically says "no splenomegaly,
13	A. Yes. I would agree. That's	13	no enlarged spleen on exam," that would
14	that's his assessment. He said he's not sure	14	make it very clear that he's basing this
15	why it is low.	15	on his physical exam.
16	Q. And as of 10/27/2016, his treating	16	BY MR. VAUGHN:
17	physician, Dr. Sanders, specifically says,	17	Q. If there was an enlarged spleen on
18	"There is no appreciable splenomegaly,	18	imaging, is the radiologist supposed to note that?
19	"correct?	19	
20	A. Yes, yes. He does say that, and	20	MS. ROSE: Object to form.
21	what I interpret that to mean is he, on	21 22	THE WITNESS: Yeah. I I I
22	physical exam, does not appreciate an enlarged	23	had mentioned before that there is quite a
23 24	spleen. Q. Even though he just had imaging	23	range in quality and expertise of
25	Q. Even though he just had imaging done months prior?	25	radiologists, as there are in any field. You know, I mean, I'm sure it's the same
1 / 1	done months prior:	∠೨	1 ou know, 1 mean, 1 m suit it 8 me same

	Page 302		Page 304
1	with lawyers.	1	
2	So you have some radiologists that		Dr. Mele who commented on the splenomegaly.
3	are extremely good at what they do and	3	Dr. Chernyak didn't comment on the spleen at
4	some who are maybe they're more	4	all. They're both in agreement that there's
5	generalists where they read a wide variety	5	cirrhosis, but only Dr. Mele specifically
6	of different types of imaging but they	6	commented on the spleen size, and he measured
7	don't specialize in body radiology.	7	it at 16 centimeters.
8	And then sometimes they they	8	I think I mentioned previously
9	don't or they're not really attending	9	that, you know, above 12 centimeters is
10	to a specific area of the body, or they're	10	regarded to be an abnormally large spleen. So
11	really attending to an area in response to	11	that's it's not really close to that
12	the reason for the imaging study.	12	threshold. I mean, a 16-centimeter spleen is
13	So yes. I think best practice	13	it's it's clearly enlarged. It's very
14	would be to do a detailed review of all	14	clearly enlarged. That's all I can say. It's
15	the organ systems that you see on, you	15	very clearly enlarged.
16	know, an abdominal CT, for instance, and	16	So I apologize for the for that
17	then to comment accurately on what you	17	clarification.
18	think is present or absent.	18	Q. You're fine. All right.
19	But it is in very common, you know,	19	Going back to your expert report,
20	in my practice, where, you know, a	20	which is Exhibit 1
21	radiology report may not note something	21	A. I apologize. Give me just a
22	that is, in fact, there that is later	22	moment. I I accidentally closed the link.
23	corrected or identified in retrospect by a	23	Okay. I think I've got it.
24	more qualified radiologist or after a	24	Q. Okay. I'm on page 9.
25	discussion with another physician who may	25	A. Okay.
			•
1	Page 303		Page 305
1	Page 303 have reviewed it who then discusses it	1	Page 305 O. And here on 7/17/2018, his AST
$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	have reviewed it who then discusses it	_	Q. And here on 7/17/2018, his AST
2	have reviewed it who then discusses it with the radiologist and they would amend	1 2 3	Q. And here on 7/17/2018, his AST spikes to 440 and ALT to 429.
2 3	have reviewed it who then discusses it with the radiologist and they would amend the report and say, you know, after	2 3	Q. And here on 7/17/2018, his AST spikes to 440 and ALT to 429. What is the significance of that,
2 3 4	have reviewed it who then discusses it with the radiologist and they would amend the report and say, you know, after re-review there is, in fact, splenomegaly	2 3 4	Q. And here on 7/17/2018, his AST spikes to 440 and ALT to 429. What is the significance of that, if any?
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Page 308 Page 306 1 A gallstone can migrate into the common bile 1 quickly return to their previous baseline. So 2 his labs on 7/25, they come back down to an AST 2 duct and cause a blockage. And so the bile has 3 nowhere to go. It can't flow out into the 3 of 66, ALT of 79, total bilirubin of 1.1, which 4 intestines like it would normally. So it backs 4 is in the range of what his previous baseline 5 up into the liver and causes acute abrupt 5 prior to this issue was. injury to the liver cells, the hepatocytes. 6 So I think that he had a stone that And they spill out a lot of AST and ALT. 7 7 was transiently obstructing the common bile 8 And the bilirubin also comes up 8 duct causing his symptoms in these labs that 9 because it's backing up, essentially, into the spontaneously passed. That's the -- excuse 10 blood. So you -- that constellation of 10 me -- that's the assessment that Dr. Hooks has 11 findings is very, very, very suggestive of a 11 as well. 12 stone that has become obstructed in the -- it's 12 And I apologize for going on about 13 this at such length, but the last thing I'll 13 obstructed in the common bile duct. 14 14 say is I -- I drew a contrast to -- to what the And that fits his clinical 15 presentation too because he -- Mr. Roberts had 15 plaintiff expert witness, Dr. Siddiqui, had 16 stated here. I mean, she -- she was basically 16 gone to the emergency department with abdominal 17 pain radiating to the back, which is a classic 17 positing in her deposition that these labs in 18 description of, you know, gallbladder or bile 18 July of 2018 where the AST and the ALT spiked 19 duct-related pain. Based on the way the nerves would -- was -- was related to aggressive 20 work in the abdomen, they're not very specific 20 hepatocellular carcinoma, which I think is an 21 in the way that they route pain signals. So 21 important, you know, landmark to -- an 22 it's very common for patients to experience 22 important flag to plant here because she is 23 abdominal pain and back pain when this issue is 23 really imputing that he would have had hepatocellular carcinoma on the basis of his 24 happening. 24 25 25 NDMA exposure in a very short time interval. So to me, this all fits very Page 307 Page 309 1 cleanly as the likely explanation. And 1 I think we had -- we had said that, Dr. Hooks was so concerned about this, that 2 you know. So this has been a less -- less than 3 he -- I believe he pursued an endoscopic 3 a year of exposure to NDMA-contaminated 4 ultrasound to look for a gallstone. Valsartan, and she was attributing these labs 5 Yeah. So I think I've noted that 5 to hepatocellular carcinoma. 6 there a couple lines lower on the page. On Q. At this point it would have been 6 7/19 he performed an endoscopic ultrasound and approximately two years, correct, of exposure? an esophagogastroduodenoscopy. You know, he 8 A. Oh, I'm sorry. Yes. I apologize. did this to look at the bile duct with an 9 I -- I misspoke. 10 10 ultrasound from the inside to look for a stone. It's -- yes. This would have been -- yes. You're right. I apologize. It 11 He did not find a stone. So that's when he 11 would have been about two years of exposure. 12 says there's no evidence of a 12 And you said his labs returned --13 choledocholithiasis. 13 dropped back down. 14 What that typically means is that 14 15 the stone that was there that was causing the 15 Which labs are you referencing? 16 obstruction has passed, and that happens very 16 A. So a little bit below the highlight 17 commonly. These might be transient that you have there, so 7/25/18, the labs were 17 18 obstructions. They cause a big problem. They AST 66, ALT 77, total bilirubin 1.1. 18 19 cause a lot of pain. People go to the 19 Up here on 7/18/2018, is this the 20 emergency department because the pain is so first time he was actually diagnosed with 20 21 bad. You see these constellation of labs. And splenomegaly by one of his treating physicians? 21 22 by the time you do the ultrasound, the stone 22 MS. ROSE: Object to the form. THE WITNESS: This is the first 23 may have spontaneously passed. 23

time in the record where splenomegaly, I

think, was specifically referenced, I

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And what -- what additionally

25 supports to that is the fact that his labs very

1 think, in a clinical note. I think that 2 is the case. 3 BY MR. VAUGHN: 4 Q. And even here in 7/18/2018, they're 5 still just saying possible changes of cirrhosis as of the liver. Not that he had — he's still are of the liver. Not that he had — he's still are of the liver. Not that he had — he's still are of the liver. Not that he had — he's still are of the liver. Not that he had — he's still are of the liver. Not that he had — he's still are of the liver. Not that he had — he's still are of the liver. Not that he had — he's still are of the liver. Not that he had — he's still are of the liver. Not that he had — he's still are of the liver. Not that he had — he's still are of the liver. Not that he had — he's still are of the liver. It has been diagnosed with cirrhosis as of the liver. This is — 10 look at Dr. Hooks or linical note. This is — 11 I don't think this is from a direct imaging that the think this is from a direct imaging that the had or he's in this clinical context of an elevated FIB-4, and a cellining platelet count, plus multiple imaging features of cirrhosis and portal the declining platelet count, plus multiple imaging features of cirrhosis and portal the declining platelet count, plus multiple imaging features of cirrhosis and portal the declining platelet count, plus multiple imaging features of cirrhosis and portal the declining platelet count, plus multiple imaging features of cirrhosis and portal the declining platelet count, plus multiple imaging features of cirrhosis and portal the declining platelet count, plus multiple imaging features of cirrhosis and portal the declining platelet count, plus multiple imaging features of cirrhosis and portal the declining platelet count, plus multiple imaging features of cirrhosis and portal the declining platelet count, plus multiple imaging features of cirrhosis and portal the declining platelet count, plus multiple imaging features of cirrhosis and portal the declining platelet count, plus multiple imaging features of cirrhosis and portal the de		Page 210		Page 212
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21 dus diffe and prior. 21 dock like the chimosis was inote severe than in	21	this time and prior.	21	look like the cirrhosis was more severe than in
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23 don't I don't get he the sense that 23 A. You can't really make a	23	don't I don't get he the sense that	23	
24 Mr. Roberts was definitively told, you 24 determination, quote/unquote, of how, you know,	24	Mr. Roberts was definitively told, you	24	• •
25 know, on 7/18/2018 that he definitely had 25 "severe" the cirrhosis is. You can	25	know, on 7/18/2018 that he definitely had	25	"severe" the cirrhosis is. You can

Page 314 1 determine -- you can infer how bad the portal 1 previously there's a very large vein that goes 2 hypertension may become. But it's -- it's 3 oftentimes a little bit more binary from a 4 cirrhosis standpoint on -- on imaging. 5 So, you know, his -- there is 6 evidence that his portal hypertension is likely 6 then go into the liver. worse in 2018, and the evidence there is that 7 7 8 his spleen size is probably a little larger 8 than it was in 2016 when Dr. Mele measured it 9 10 at 16 centimeters. So in 2018 it was measured 10 11 at 17.3 centimeters. So that suggests the 11 12 portal hypertension is likely a little bit 12 13 worse. But the cirrhosis a-- as s a binary 14 feature, the cirrhosis is present on both 15 imaging studies. Q. So does the an- -- excuse me. 16 17 Does your answer change any of the 17 18 fibrosis? 18 19 pipe. Was Mr. Roberts' fibrosis any worse 19 20 in the imaging in 2018 versus 2016? 20 21 A. So, you know, fibrosis, like I 21 22 said, you know, the terminal staging of 22 23 fibrosis is cirrhosis. F4 by the METAVIR 23 connected by a branch of the portal vein to the staging is -- is cirrhosis. There's no 24 25 fibrosis staging that goes beyond that. 25 liver.

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2 into the liver called the portal vein, and that 3 drains -- that blood supply kind of drains the 4 intestines and a lot of the gut. So many 5 different veins feed into the portal vein and In the liver the portal vein, then, branches out into many, you know, microscopic small branches of the portal vein. What happens in cirrhosis is the scarring happens very diffusely, you know, throughout the liver, and the scarring can 13 basically squeeze on those microscopic portal 14 veins. It's almost like a plumbing problem 15 where you can image there's a pipe going 16 through the liver. The scar in the liver is sort of squeezing around the pipe. So you get a pressure backup upstream, you know, of the So you look for specific signs of enlargement of particular veins that normally would not be abnormally enlarged, and you -and the other thing is the spleen is directly

Page 315

2 by definition he has F4 fibrosis. There can be accumulating fibrosis beyond that; but from a diagnostic standpoint of cirrhosis, there's no 5 additional stage. So -- so yeah. There's nowhere 6 7 else in the scale to place him. Like, he has 8 cirrhosis in both settings. And then beyond that, the things you're looking for are 10 evolution of worsening portal hypertension. So yeah. So it doesn't really make 11 12 sense to me, I guess, per se, to say that the, 13 quote/unquote, "the cirrhosis appearance is 14 more severe in one imaging than the other." 15 It's more features of the portal hypertension 16 that become more salient once the cirrhosis is 17 already diagnosed. 18 Q. And what is the evidence of portal 19 hypertension? 20 So there are multiple lines of 21 portal hypertension. Maybe if I just very 22 briefly explain what it is it'll make it pretty clear hopefully what I'm referring to on the

But basically, there's -- I said

So if cirrhosis is present in 2014,

1 So the spleen one of the organs

2 that is very directly impacted by this problem.

3 When there's a lot of scar, there's a squeezing

4 of the pipe, the pressure backs up into the

spleen, among other areas. The spleen gets

congested because of that pressure and begins

7 to enlarge. So that's why the splenomegaly is

8 very relevant.

9 Another very important feature is 10 something called an umbilical vein. This is a feature that both expert radiologists from 12 plaintiff and -- and the defense side both 13 com- -- acknowledge and comment on is that Mr. Roberts has something called a recanalized 15 umbilical vein. What that means is he has an 16 umbilical vein that is open. You can see that 17 it has blood flowing through it. Normally that does not happen in 18 19

adults. If the umbilical vein is as -- as the 20 name would suggest, it's -- it's seen in infants when you're first -- when someone is 21 born, they're attached to the mother through

23 the umbilical vein and, you know, the umbilical, you know, artery as well. 24

25 And so but that as -- as you grow

80 (Pages 314 - 317)

imaging.

24

25

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	Page 318		Page 320
1	into into, you know, even in pediatrics, it	1	know, I think wherever I was able to calculate
2	closes up relatively quickly from my	2	a FIB-4, I think I did so.
3	recollection. But certainly in an adult that	3	So, you know, in December of 2018,
4	should not be open. It's entirely closed. You	4	he had the requisite labs sent to calculate a
5	only see that open up when there is portal	5	FIB-4; but oftentimes, he might have piecemeal,
6	hypertension. It's pathognomonic for portal	6	like, he might have an AST and an ALT sent off,
7	hypertension.	7	but not the platelet count, so I wasn't able to
8	Pathognomonic just means that if	8	compute a FIB-4.
9	you see it, it is it is an indication that	9	So, you know, I'm not giving an
10	there's portal hypertension present. You will	10	exhaustive summary of all of his labs, but I'm
11	not see it if there's no if there's no	11	trying to highlight the ones that were most
12	portal hypertension.	12	relevant and pertinent to my opinion.
13	So Mr. Roberts has all of these	13	MS. ROSE: Mr. Vaughn, just for the
14	features in 2016. He has all these features in	14	record, we've been going for over an hour.
15	2018. And the spleen being enlarged, it's	15	So I just wanted wanted to let you know
16	it's also sort of a filter of sorts where it	16	whenever you reach a good stopping point.
17	traps platelets. So the larger the spleen	17	MR. VAUGHN: I was just about to
18	gets, the lower the platelet count is expected	18	say, if you would like to take a break,
19	to get as well, which is why if things tend to	19	I'm at a good stopping point.
20	trend downward over time as the portal	20	MS. ROSE: Doctor, would you like
21	hypertension worsens.	21	to take a break?
22	So I'm relying on those things.	22	THE WITNESS: Sure.
23	I'm relying on the platelet count, the spleen	23	THE VIDEOGRAPHER: Off the record
24	size, the recanalized umbilical vein. Those	24	at 3:51.
25	are the primary pieces of evidence on these	25	(Whereupon, a break was taken.)
	Page 319		Page 321
1	scans that there is very clearly portal	1	THE VIDEOGRAPHER: We are back on
2	hypertension present.	2	the record at 4:03.
3	Q. And the spleen being enlarged, I	3	MR. VAUGHN: All right. Kathryn,
4	think you were just mentioning, that's like	4	if we could drop in the 6/19/2017 record,
5	congestion. So, like, fluid is backing up, and	5	I believe this will be Exhibit 14.
6	there's congestion that makes the spleen	6	(Whereupon, Exhibit 14, Medical
7	enlarged.	7	records, Bates labeled Restricted
8	Is that the correct way to think of	8	Confidential Information
9	it?	9	GRobertsJr-AMG-000032 through Restricted
10	A. Yeah. I think, you know, that's	10	Confidential Information
11	that's a yeah. That's a that's a very	11	GRobertsJr-AMG-000036, was marked for
12	simplistic way is to explain it is, yes, it's	12	identification.)
13	under high pressure. The spleen experiences	13	MS. AVILA: Yes. It's in there
14	that pressure and will start to enlarge.	14	now.
15	Q. And did you continue reviewing	15	THE WITNESS: Okay. I have it up.
16	Mr. Roberts' labs after he was diagnosed with	16	BY MR. VAUGHN:
17	liver cancer?	17	Q. This is the $6/19/2017$, correct,
		18	Doctor?
18	A. Yes, I did. I think I you know,		A \$7
18 19	I highlighted ones along the way that I thought	19	A. Yes.
	I highlighted ones along the way that I thought were relevant to his clinical course. You	19 20	Q. And he was having an office visit
19 20 21	I highlighted ones along the way that I thought were relevant to his clinical course. You know, certainly, for instance, you know, I	20 21	Q. And he was having an office visit for the thrombocytopenia?
19 20 21 22	I highlighted ones along the way that I thought were relevant to his clinical course. You know, certainly, for instance, you know, I highlight some of his tumor-related markers,	20 21 22	Q. And he was having an office visit for the thrombocytopenia?A. Yes, yes. Well, I guess there's
19 20 21 22 23	I highlighted ones along the way that I thought were relevant to his clinical course. You know, certainly, for instance, you know, I highlight some of his tumor-related markers, you know, where I thought was relevant.	20 21	Q. And he was having an office visit for the thrombocytopenia?A. Yes, yes. Well, I guess there's multiple multiple diagnosis codes that are
19 20 21 22 23 24	I highlighted ones along the way that I thought were relevant to his clinical course. You know, certainly, for instance, you know, I highlight some of his tumor-related markers, you know, where I thought was relevant. His alpha-fetoprotein, I think I	20 21 22 23 24	Q. And he was having an office visit for the thrombocytopenia? A. Yes, yes. Well, I guess there's multiple multiple diagnosis codes that are there. So among other ones, there's
19 20 21 22 23	I highlighted ones along the way that I thought were relevant to his clinical course. You know, certainly, for instance, you know, I highlight some of his tumor-related markers, you know, where I thought was relevant.	20 21 22 23	Q. And he was having an office visit for the thrombocytopenia?A. Yes, yes. Well, I guess there's multiple multiple diagnosis codes that are

1	Page 322	1	Page 324
$\frac{1}{2}$	Q. Thank you for that clarification.	1	specifically noted in his his office note.
2	A. Okay.	2	MR. VAUGHN: And then, Kathryn, can
3	Q. And his doctor notes that he has a	3	you drop the 2000 the 12/13/2018. And
4	history of thrombocytopenia based on his last	4	what exhibit is this going to be?
5	visit of October 2016, correct?	5	I'm off on my numbers. I'm sorry.
6	A. Yes.	6	MS. AVILA: Yes. This will be
7	Q. Okay. And October 2016, that's	7	Exhibit 15.
8	after he started NDMA-contaminated Valsartan,	8	MR. VAUGHN: It is 15. Thank you.
9	correct?	9	(Whereupon, Exhibit 15, Medical
10	A. Yes.	10	records, Bates labeled Restricted
11	Q. Okay. And if we go to the actual	11	Confidential Information
12	labs he's referencing for thrombocytopenia, it	12	GRobertsJr-SouCC-000235 through Restricted
13	shows a platelet count of 127, correct?	13	Confidential Information
14	A. I'm scrolling through.	14	GRobertsJr-SouCC-000238, was marked for
15	Yes. I see that. 127, yes.	15	identification.)
16	Q. And at reference range here, that	16	BY MR. VAUGHN:
17	bottom end of normal, is 130, correct?	17	Q. All right. Doctor, this will be
18	A. Yes. That's the reference range	18	the 12/3/2018 visit for Mr. Roberts, correct?
19	reported by this lab, again, with the same	19	A. Yes, 12/3/2018, yes.
20	caveats that I provided, you know, previously	20	Q. And at this point, he has been
21	about my my interpretation about the	21	diagnosed with Stage 3A hepatocellular
22	platelet count.	22	carcinoma, correct?
23	Q. And the lab is noting that the 127	23	A. Yes.
24	this time is abnormal, correct?	24	Q. What does Stage 3A hepatocellular
25	A. Yes.	25	carcinoma indicate?
	Page 323		Page 325
1	Q. And is that the first time that	1	A. This indicates that he does not
2	we've seen the lab actually say that his	2	have early stage HCC. This is an HCC that is
		4	have early stage free. This is an free that is
3	throm that his platelet count was abnormal?	3	generally beyond transplant criteria.
3 4	A. I think that's the case. Yeah. If		
	•	3	generally beyond transplant criteria.
4	A. I think that's the case. Yeah. If	3 4	generally beyond transplant criteria. I'll say that, you know, in our
5	A. I think that's the case. Yeah. If I recall I'm trying to recall the reference.	3 4 5	generally beyond transplant criteria. I'll say that, you know, in our practice we we typically use a different
4 5 6	A. I think that's the case. Yeah. If I recall I'm trying to recall the reference. Yeah. I think in the November 2015 one we	3 4 5 6	generally beyond transplant criteria. I'll say that, you know, in our practice we we typically use a different staging schema these days. It's possible
4 5 6 7	A. I think that's the case. Yeah. If I recall I'm trying to recall the reference. Yeah. I think in the November 2015 one we looked at together when it was 137 I can't	3 4 5 6 7	generally beyond transplant criteria. I'll say that, you know, in our practice we we typically use a different staging schema these days. It's possible that you know, I think in 2018, perhaps, a
4 5 6 7 8	A. I think that's the case. Yeah. If I recall I'm trying to recall the reference. Yeah. I think in the November 2015 one we looked at together when it was 137 I can't even recall what the reference range was for	3 4 5 6 7 8	generally beyond transplant criteria. I'll say that, you know, in our practice we we typically use a different staging schema these days. It's possible that you know, I think in 2018, perhaps, a different nomenclature was commonly used.
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4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	A. I think that's the case. Yeah. If I recall I'm trying to recall the reference. Yeah. I think in the November 2015 one we looked at together when it was 137 I can't even recall what the reference range was for that lab. Q. Okay. A. Was that one 1 140? Q. That one was 130. The one where his platelets were 174, the lower limit of normal was 140. A. Gotcha. Yes. Then I would I would agree with you. This is the first time that the lab has flagged this as abnormal. Q. And the doctor, his treating scratch that. Mr. Roberts' treating physician is	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	generally beyond transplant criteria. I'll say that, you know, in our practice we we typically use a different staging schema these days. It's possible that you know, I think in 2018, perhaps, a different nomenclature was commonly used. These days we used something called the BCLC staging, the Barcelona Clinic Liver Cancer criteria staging; but I see it's not framed in that fashion here. This is something called the NCCN staging. So I can't recall, like, the specific delineations of thresholds that move someone from Stage 3A, Stage 3B. But generally speaking, this is not an early stage hepatocellular carcinoma, and it's not one that can be, you know, generally cured with liver transplantation, unfortunately.
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4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. I think that's the case. Yeah. If I recall I'm trying to recall the reference. Yeah. I think in the November 2015 one we looked at together when it was 137 I can't even recall what the reference range was for that lab. Q. Okay. A. Was that one 1 140? Q. That one was 130. The one where his platelets were 174, the lower limit of normal was 140. A. Gotcha. Yes. Then I would I would agree with you. This is the first time that the lab has flagged this as abnormal. Q. And the doctor, his treating scratch that. Mr. Roberts' treating physician is not considering him thrombocytopenic until his lab is actually abnormal, correct? A. Yeah, that seems to be the case.	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	generally beyond transplant criteria. I'll say that, you know, in our practice we we typically use a different staging schema these days. It's possible that you know, I think in 2018, perhaps, a different nomenclature was commonly used. These days we used something called the BCLC staging, the Barcelona Clinic Liver Cancer criteria staging; but I see it's not framed in that fashion here. This is something called the NCCN staging. So I can't recall, like, the specific delineations of thresholds that move someone from Stage 3A, Stage 3B. But generally speaking, this is not an early stage hepatocellular carcinoma, and it's not one that can be, you know, generally cured with liver transplantation, unfortunately. Q. What was the other staging that you talked about that can be used? A. It's called the BCLC staging. It's
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. I think that's the case. Yeah. If I recall I'm trying to recall the reference. Yeah. I think in the November 2015 one we looked at together when it was 137 I can't even recall what the reference range was for that lab. Q. Okay. A. Was that one 1 140? Q. That one was 130. The one where his platelets were 174, the lower limit of normal was 140. A. Gotcha. Yes. Then I would I would agree with you. This is the first time that the lab has flagged this as abnormal. Q. And the doctor, his treating scratch that. Mr. Roberts' treating physician is not considering him thrombocytopenic until his lab is actually abnormal, correct?	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	generally beyond transplant criteria. I'll say that, you know, in our practice we we typically use a different staging schema these days. It's possible that you know, I think in 2018, perhaps, a different nomenclature was commonly used. These days we used something called the BCLC staging, the Barcelona Clinic Liver Cancer criteria staging; but I see it's not framed in that fashion here. This is something called the NCCN staging. So I can't recall, like, the specific delineations of thresholds that move someone from Stage 3A, Stage 3B. But generally speaking, this is not an early stage hepatocellular carcinoma, and it's not one that can be, you know, generally cured with liver transplantation, unfortunately. Q. What was the other staging that you talked about that can be used?

- 1				
		Page 326		Page 328
	1	expert report if it's of interest, but it's	1	increased a little bit from the last platelet
	2	called the Barcelona Liver sorry, Barcelona	2	we had at the time of his cancer diagnosis,
	3	Clinic Liver Cancer classification. That is	3	correct?
	4	really the state-of-the-art classification	4	A. Yes. It is slightly higher, I
	5	schema that's used for for staging HCC in	5	think, than the previous one we looked at
	6	the modern era, like the current era of	6	together.
	7	practice. It also helps inform management and	7	Q. Do you have any explanation for why
	8	treatment of HCCs of different stages.	8	it would have increased some at this point?
	9	Q. And when did BCLC become will the	9	A. Sure. Sorry. What was the
	10	common staging to use?	10	previous I'm trying to remember the degree
	11	A. Let me tell you. So the most	11	of change. Let's see if I can find that. All
	12	recent iteration of the BCLC, the one that we	12	right.
	13	use currently, it's relatively recent. So this	13	So it was one in 2015 it was
	14	was published in the Journal of Hepatology in	14	that. So ins 2016 it was 127. I think that's
	15	2022. The first author is, I think it's Marta	15	the last one we reviewed.
	16	Reig, R-E-I-G. It's a 2022 publication with	16	Is that your recollection as well?
	17	the current the current BCLC staging	17	Sorry. I don't mean to interrogate
	18	criteria, which I understand postdates this	18	you.
	19	note.	19	Q. No, no. You're fine. We we did
	20	Q. And does Stage 3A correspond to any	20	review that one, yes.
	21	BCLC?	21	A. Okay. Regardless, I mean, yes.
	22	A. Yeah. I I mean, I'd have to	22	It's changing on the order of maybe 20 points
	23	look specifically to confirm, but I'm fairly	23	or so or maybe less.
	24	certain that this would correspond to a BCLC	24	Yeah. So I think I mentioned
	25	Stage B hepatocellular carcinoma.	25	before that, you know, platelet counts, they
t		Page 327		Page 329
	1	Q. And do you see here where the	1	can fluctuate very commonly based on a lot of
	2	doctor says, "The CBC results were reviewed,	2	different factors.
	3	and counts were noted to be within normal	3	So, you know, for instance, time of
	4	limits"?	4	day is one factor. I mean, if you check
	5	A. Yes, I see that.	5	someone's platelet count in the afternoon, it
	6	Q. And that that would indicate	6	tends to be a little bit higher than in the
	7	that this physician, his treating physician,	7	morning. Things can vary based on your
	8	believes that his platelets are within normal	8	hydration status. So if you're more
	9	limits on 12/3/2018, correct?	9	dehydrated, your platelet count will be usually
	10	A. Yeah. That's what this statement		a little bit higher because of something called
	11	says. I would need to see what the CBC	11	hemoconcentration.
	12	actually is. I don't know if they have the	12	Or if you have if you're
	13	platelet count there reported or other values.	13	infected, that's a stress state that can drive
	14	Q. Right here, 142.	14	the platelet count a little bit higher. There
	15	So his treating physician is	15	are certain medications, like, you know,
	16	considering a 142 platelet count from this lab	16	Prednisone that can cause something called
	17	to be normal, correct?	17	demargination that drives the platelet count
	18	A. That's that appears to be their	18	higher. There's lots and lots of things
	19	interpretation. It may be the case that this	19	that that can cause platelet counts to
	20	1.1. ''1. 1. 1	20	Classification and the state of

83 (Pages 326 - 329)

20 fluctuate from one lab test to another, which21 is why, you know, again, I keep emphasizing the

22 importance of looking at trends in platelet

23 counts and not really relying on one particular

You know, to me, this is -- this is

25

24 instance.

25

24 thrombocytopenia.

20 lab similarly has a lower end of normal, maybe

And his platelets have now

21 140 or something where it doesn't flag it as
22 abnormal. But again, to hepatologists like

23 myself, that is abnormal. It is still

	Page 330		Page 332
1	a fluctuation that, to me, is still abnormal.	1	record, correct?
2	It's still low. It's not dramatically	2	THE WITNESS: I apologize.
3	different, I wouldn't say, from his prior	3	MS. ROSE: I'm sorry. I just
4	platelet count that we reviewed together; but,	4	you said it's a 2019, and then
5	you know, at this time he's, you know, he's	5	BY MR. VAUGHN:
6	certainly sicker. He probably has, you know,	6	Q. I think she was probably
7	some degree of stress response that's occurring	7	interrupting you because you said that he had
8	in the setting of his somewhat advanced cancer	8	ascites at this time.
9	at this stage. So it's not unusual to see the	9	Did he have ascites at this time in
10	platelet count come up a little bit in that	10	December of 2018?
11	setting.	11	A. No, no. He did not. I apologize.
12	=	12	
13	•		I got mixed up with the year. I know in 2019
14	variation to kind of just be in the normal	13	he had ascites, yeah. Let let me allow
15	variation that you would see from test to test. A. Yeah	14 15	me to correct that. I apologize. Yeah. At this time he did not have
16	MS. ROSE: Object to the form.	16	ascites. This is this is 2018.
17	THE WITNESS: I'm sorry.	17	So yeah. I mean, it's hard to mean
18	Yeah. It doesn't strike me as	18	to determination of, you know, is the portal
19	unusual. It doesn't really change any of	19	hypertension better or worse. But I he
20	my opinions about why the platelet count	20	doesn't really have any reasons for it to be
21	is is continues to be low in my	21	better. So it's likely that his portal
22	view.	22	hypertension is a little bit worse. But he is
23	So yeah. This is this is a	23	in a higher state of kind of basal stress in
24	fluctuation that doesn't really have much	24	the setting of of having this cancer.
25	clinical significance in my opinion.	25	So it's not unusual to see platelet
1	Page 331	1	Page 333
	BY MR. VAUGHN:		fluctuations, you know, in his this range. And
2	Q. Would it mean that his portal	_	I think that even shortly after this one
3	hypertension is doing better at this point?	3	this is from 12/3 you know, as as an
4	A. No, I wouldn't say that. In		illustration he has labs checked on again 12/18
5	fact sorry. This 20 this is December		of 2018, and his platelet count is 126.
6	2019, right?	6	So this does fluctuate, and, you
7	Q. Uh-huh.	7	know, you're trying to get a sense of the
8	A. I apologize. I was looking for one	8	trends and the general range where it is
9	thing in my note.		currently. So I don't read too much into this
10	So it's actually it's very clear	10	isolated platelet count bumping a little bit
11	that his portal hypertension is worse at this	11	relative to the previous value.
12	time because at this point in his history, he	12	Q. But you do read into it bumping
13	has developed decompensated cirrhosis. He has	13	down a little bit when it does?
14	manifested ascites as a clinical symptom of his	14	A. No, I don't. I don't. I I
15	cirrhosis, which he	15	like I said, I'm just I highlight that just
16	MS. ROSE: Can I I'm I'm	16	to show you it can fluctuate up and down. If
17	sorry. I feel like there's some confusion	17	the trend over time is it is gradually
18	because I feel like you both just said	18	dropping lower and lower. You know, I think
19	this was a 2019 record.	19	126 might have been, for instance, like, a new
20	Are we still looking at I'm	20	low value for him.
21	sorry. I don't mean to interrupt.	21	But in my determination, I've
22	But are we still looking at	22	already it's already established that he has
23	MR. VAUGHN: I haven't changed the	23	cirrhosis and portal hypertension. So, you
24 25	exhibit.	24	know, to me, perseverating on the platelet
	MS. ROSE: Oh, so it's a 2018	25	count is not as relative as managing the

1 clinic 2	Page 334		D 224
1			Page 336
1 7	cal symptoms and the cancer at this stage.	1	Mr. Roberts', last dose of NDMA-contaminated
	It's not really disputed that he	2	Valsartan with HCTZ was filled on 6/13/2018?
	irrhosis and portal hypertension by	3	A. Yes. That yeah. That appears
	ody at this point. And so the platelet	4	to be the case from this document.
	t is, you know, it's not really the most	5	Q. And it was a 90-day fill, correct?
_	ortant thing in his record in my view.	6	A. Yes.
$\int_{0}^{\infty} Q$		7	Q. And 90 days after 6/13/2018 would
1 *	to this diagnosis?	8	put us somewhere around the middle of September
9 A	j j	9	2018?
	important. I mean, they're important, of	10	A. Yes, that sounds about right.
	se. I think the area in his record where I	11	Q. And his next CBC his platelets went
	they're probably most important are in	12	up, correct?
	tating and understanding of when he	13	A. Yes, his next CBC, the platelets
1	y had cirrhosis and what should have	14	are up a little bit.
_	ed prompt him to have been evaluated by,	15	Q. And we discussed earlier how HCTZ
	ly, a hepatologist to try to establish the	16	can impact platelets, correct?
	nosis. And then trying to establish, you	17	MS. ROSE: Object to the form.
	v, and understand what degree of portal	18	THE WITNESS: You showed me a case
	rtension he may have.	19	report from 40 years ago that, you know,
20	At this point it's very clear that	20	that basically made, you know, the
	as evidence of portal hypertension, the	21	observation that somebody who was started
	nomegaly, the recanalized umbilical vein.	22	on HCTZ was observed to have a platelet
23	So, you know, I have an	23	count that went down. And then they
1	rstanding already of why his platelet count	24	stopped it, and it went back up a little
25 is in t	this range. So sure, the platelet count	25	bit.
	Page 335		Page 337
	continue to trend down gradually; but if it	1	And, you know, I apologize. Just
	to go up a little bit, I wouldn't suddenly	2	to add one more parenthetical, yeah, as I
	hat, okay, his portal hypertension is gone	3	mentioned a moment ago, the subsequent
	use that's not the way that cirrhosis	4	platelet count that was checked very
_	ophysiology works.	5	shortly afterwards was, once again, 126.
6 Q	1 7	6	So, you know, if the implication
	ds to see if any medications were dis	7	that you might be suggesting is that
	ch that.	8	stopping the HCTZ is why the platelet
9	Did you review Mr. Roberts'	9	count went up by, you know, 15 or 16
_	macy records to see if any medications were	10	points, that would not be a viable
	ontinued right before his platelet count	11	explanation given that, you know, only,
	ased?	12	you know, two weeks later the platelet
13	MS. ROSE: Object to the form.	13	count is back to 126 while he's still off
14	THE WITNESS: As before, I reviewed	14	the medication.
	s his, you know, medications	15	So I don't I don't view that to
	roughout his course. But, you know, I	16	be, you know, compelling.
	an't recall specifically if there was a	17	BY MR. VAUGHN:
	edication that was stopped, you know,	18	Q. Did you do any research in coming
_	rior to this one. But I'm happy to	19	to your expert opinions if NDMA could cause the
	eview that with you.	20	spleen to enlarge?
_	MR. VAUGHN:	21	A. That's a good question.
22 Q	-	22	I don't recall coming across
	h was his pharmacy records. And let's see	23	studies that specifically were investigating
24 here.		24	NDMA exposure and spleen size.
25	Would you agree with me that his,	25	MR. VAUGHN: Kathryn, can you drop

	D 440		D 46
1	Page 338 in 2008 WHO for Exhibit 16.	1	Page 340 MS. ROSE: Object to the form.
2	MS. AVILA: Yes. It's in there.	2	THE WITNESS: Yeah. So so the
3	It's Exhibit 16.	3	statement here, it's actually not
4	(Whereupon, Exhibit 16, Document	4	commenting on enlargement of organs. It's
5	entitled "N-Nitrosodimethylamine in	5	talking about congestion. That doesn't,
6	Drinking-water, Background Document for	6	you know, necessarily mean that there's
7	Development of WHO Guidelines for	7	going to be enlargement of an organ.
8	Drinking-water Quality", was marked for	8	But, you know, I acknowledge, you
9	identification.)	9	know, I'd have to review the study, the
10	BY MR. VAUGHN:	10	particles to understand the methodology.
11	Q. All right. Doctor, this is from	11	But I take them I take them at their
12	the WHO.	12	word in this report that with high dose
13	Do you know what the WHO is?	13	NDMA exposure, if they see evidence of
14	A. Yes. It's the World Health	14	increased blood flow in different organs,
15	Organization.	15	I don't have any intrinsic, you know,
16	Q. Okay. And they put this out in	16	reason to doubt that in in this study
17	2008 called N-Nitrosodimethylamine in	17	in rodents.
18	Drinking-water.	18	BY MR. VAUGHN:
19	A. Okay.	19	Q. And you say that you would need to
20	Q. Have you seen this document before?	20	review the study.
21	A. I'm not sure if I saw this specific	21	You didn't review this study prior
22	one. I may have. I did I did review	22	to coming to your expert opinions, correct?
23	some I certainly reviewed a number, you	23	A. I don't recall the specific study.
24	know, several different NDMA-related	24	It's very possible that I did come across it,
25	publications from WHO. I can't immediately	25	but I'd have to see that study I'd have to
	Page 339		Page 341
1	recall if I saw this specific one.	1	look through it again to jog my memory.
2	Q. If we go to page 8, I believe, it's	2	There were many different studies,
3	page 16 of the PDF.	3	obviously, that I reviewed. I cited a large
4	A. Okay. 16?	4	number of studies. It's hard to immediately
5	Q. Yeah. Do you see here where the	5	recall each one of them in detail.
6	World Health Organization says, "In addition to	6	Q. And just a few minutes ago, you
7	effects in the liver, congestion, excessive	7	testified that splenomegaly was caused by
8	blood, fluid content in a variety of organs,	8	congestion or excessive fluid, correct?
9	i.e. kidneys, lung, spleen, and myocardium, has	9	A. Yes. I did I explained that
10	been reported following examination of rats	10	congestion in the setting of elevated portal
11	receiving NDMA."	11	pressures can lead to growth of the spleen.
12	Were you aware of that?	12	So I I use the term "congestion"
13	A. Yeah. I don't recall coming across	13	to facilitate an understanding of what high
14	this, you know, specifically. But just kind of	14	pressures can do, but that's not meant to imply
15	reading the full context here, you know, this	15	that congestion in all cases in the absence of
16	looks like it's from an animal study of rats	16	elevated elevated pressures may translate to
17 18	who were receiving what seems like an exceptionally high dose of NDMA of, you know,	17 18	enlargement of the spleen. I was describing that specifically in the context of portal
19	3.8 milligrams per kilogram per day, which is	19	hypertension and cirrhosis.
20	an extraordinarily high dose relative to	20	Q. And these are rats that they gave
21	exposures, you know, that have been observed in	21	NDMA to. They only gave it to them for 1 to 12
$\begin{vmatrix} 21\\22\end{vmatrix}$	human studies and certainly orders of magnitude	22	weeks, right?
23	higher than what Mr. Roberts was exposed to.	23	A. Yes. They gave it to rats for 1 to
	ingilor dian what in. Robotto was exposed to.	23	
	O. And so are you disagreeing that	2.4	12 weeks.
24	Q. And so are you disagreeing that NDMA can cause the spleen to enlarge?	24 25	12 weeks. Q. And Mr. Roberts was taking NDMA for

1	Page 342 approximately two years, correct?	1	Page 344 used you know, what the role is in the
2	MS. ROSE: Object to the form.	2	scientific process to understand the relevance
	· ·		<u>-</u>
3	THE WITNESS: Yes, he was taking	3	of a drug or a new exposure and how that may or
4	NDMA for approximately two years. But the	4	may not translate to humans.
5	two, I think, important points I I	5	So I'm relying on my perspective
6	would just highlight very briefly are,	6	with that background, but but that's, you
7	again, that the magnitude dose exposure	7	know, that's my understanding of why you cannot
8	is is very, very different here; and	8	simply take a multi-week exposure in in a
9	the second important point that I think	9	rat and say that the same multi-week exposure
10	actually has not been touched upon in any	10	should have the impact in a human.
11	of the depositions I've reviewed from	11	Q. And you didn't give that expert
12	toxicologists, et cetera, is that the	12	opinion in your report, did you?
13	lifespan of a rat is very different than a	13	A. I did not give that expert opinion
14	lifespan of a human.	14	in my report. The reason I bring it up is
15	You know, rodent lifespans are on	15	because I reviewed the deposition of
16	the order of two years. So one to so,	16	Dr. Siddiqui this week where she offered that
17	you know, three weeks of exposure	17	opinion. So I'm trying to be responsive to
18	sorry. Three months of exposure 12 weeks	18	what the plaintiff expert witness stated in her
19	to, you know, in a rodent study, that's	19	report.
20	equivalent to potentially more than a	20	I I recall specifically reading
21	decade of exposure in a human. So you can't translate time for rodents one to	21	her deposition that, you know, she is saying
22		22	that, you know, in in rodents over the
23	one to humans.	23	course of weeks' long exposure and actually,
24 25	Yeah. At the top of our	24	I think that my recollection was it's really
25	deposition, I highlighted that the FDA	25	more in the order of, like, maybe three to six
,	Page 343		Page 345
1	understands this; and that's why they	1	months on the earlier side on the animal
2	frame their dose threshold exposure for NDMA in terms of a lifetime of human	2 3	literature, you might see an association between NDMA and liver cancer.
3			
5	exposure over 70 years. So it's it's a major fallacy to	5	So I'm responding to, you know, the plaintiff expert witness's statement, which,
6	try to translate a time course of exposure	6	you know, she didn't offer that opinion, to my
7	in a rat to being equivalent to a time		recollection, in her initial report. This came
8	course of exposure in a human. Three to	8	out in her deposition.
9	six months of exposure in a rat is decades	9	So I'm specifically offering that
10	of exposure time in a human. So I need to	10	opinion in response to hers.
11	make that point really, really clear.	11	Q. And did you produce any literature
12	BY MR. VAUGHN:	12	to support that opinion before this deposition?
13	Q. Are you a toxicologist?	13	A. No, I did not. I mean, I read her
14	A. No. I've stated multiple times I'm	14	deposition, I think, yesterday; and but I'm
15	not a toxicologist, but I am a clinician. I'm	15	not relying on literature that hasn't already,
16	a clinician scientist. You know, I'm	16	you know, been disclosed. I'm happy to to
17	acquainted with, you know, reviewing animal	17	offer that. If necessary, I'm happy to review
18	literature, you know, to an extent in the	18	this and supply literature if it's helpful.
19	course of my, you know, my practice as a	19	But I'm relying actually on, you
20	clinician and as a clinician scientist. And I	20	know, the FDA-related documents to as an
21	understand these principles.	21	illustration of this because the FDA very
22	You know, we get educated about	22	clearly states in their industry guidance
23	these things in medical school, you know, when	23	regarding NDMA and the threshold levels that
24	we learn about animal literature and how	24	these are the dose exposure levels for a human
1 -		l	
25	what the context in which animal literature is	25	lifespan over 70 years, where they would expect

1	Page 346	1	Page 348 BY MR. VAUGHN:
$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	to see one additional cancer per 100,000	_	
2	individuals with that exposure. And that's	2	Q. Do you know if any of the Valsartan
3	translated from from animal studies.	3	pills that Mr. Roberts ingested had higher
4	So the reason why they extend it	4	levels of NDMA in it than the FDA was aware of?
5	over 70 years is because the lifespan of a	5	MS. ROSE: Object to the form.
6	rodent is about roughly two years, and they	6	(Whereupon, Daniel Nigh joined the
7	basically do calculations, you know, from the	7	deposition.)
8	dose exposures in animal studies. They set a	8	THE WITNESS: I understand that,
9	conservative margin, and they translate that to	9	you know, Mr. Roberts' alleged exposure in
10	a human lifespan.	10	some of the NDMA-contaminated Valsartan
11	So that's why the the FDA	11	pills is above the FDA threshold limit.
12	doesn't say this dose exposure for a period of	12	BY MR. VAUGHN:
13	weeks. It's a period of decades, decades.	13	Q. It's a they're all it's al;
14	So I'm trying to contextualize	14	above the threshold limit.
15	these documents that I think all of us have	15	But are you aware if any of his
16	reviewed related to the FDA.	16	pills had more NDMA in it than the FDA even
17	Q. What was the highest level of NDMA	17	realized was in any of the Valsartan pills?
18	that the FDA was aware of in Valsartan pills?	18	MS. ROSE: Object to the form. And
19	MS. ROSE: Object to the form.	19	it's going outside the scope of his expert
20	THE WITNESS: I'd have to review	20	report.
21	you know, we can look at whether the	21	THE WITNESS: Yeah. Like I said,
22	toxicology reports I think Dr. Sawyer	22	I'm not privy to, you know, internal
23	gave the ranges. You know, I can't, you	23	company documents from ZHP related to what
24	know, give you off the top of my head,	24	they did or did not know related NDMA
25	like, what the exact number was for the	25	content in their pills.
	Page 347		Page 349
1	highest.	1	So I I don't know about that. I
2	But, you know, it's in the range	2	haven't reviewed those, you know,
3	of, if I'm just trying to recall you	3	pertaining to specific causation for
4	know, 20 micrograms was one of the higher	4	Mr. Roberts.
5	end estimates for Valsartan pills, you	5	BY MR. VAUGHN:
6	know, for certain pharmaceutical	6	Q. My question, though, is specific to
7	companies. It varied by by	7	Mr. Roberts.
8	pharmaceutical company.	8	Are you aware if any of the pills
9	BY MR. VAUGHN:	9	that he ingested had more NDMA in it than the
10	Q. Which pharmaceutical company had	10	FDA thought was the highest levels in
11	the highest levels of NDMA in their Valsartan?	11	Valsartan?
12	A. I believe that it was the the	12	MS. ROSE: Object to the form. And
13	defendant company.	13	again, this is outside the scope. What
14	Q. The ZHP?	14	the FDA knew or thought
15	A. Yes, I believe so.	15	MR. VAUGHN: If he wants to give an
16	Q. Do you know if ZHP's internal	16	opinion on the risk level that the FDA is
17	testing showed levels of NDMA higher in	17	saying, then it is relevant.
18	Valsartan than the FDA was aware of?	18	MS. ROSE: I I don't think
19	MS. ROSE: Object to the form.	19	that's what he's saying, but okay. I
20	THE WITNESS: No, I was not privy	20	I just don't see how he has any
21	to, you know, internal company documents	21	knowledge of this or is offering any
22	or reports, you know, in formulating my	22	opinion.
23	specific causation for this this	23	MR. VAUGHN: Then he can say he has
24	this case.	24	no knowledge. That's fine if he says he
		25	doesn't know.
25			

1	Page 350 THE WITNESS: Yeah. And I mean,	1	Page 352
$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$		$\frac{1}{2}$	A. Sorry. Q. If those levels existed for the
2	that's what I've stated. I'm not privy to	_	
3	these documents. I have no knowledge of	3	pills that Mr. Roberts actually ingested, is
4	that. I know what's been reported in	4	that something that you would want to see in
5	terms of the range of NDMA con you	5	coming to your opinions?
6	know, contamination. That was	6	MS. ROSE: Object to the form.
7	potential potentially identified in	7	THE WITNESS: So, again, my honest
8	those Valsartan pills.	8	impression of this case is it really would
9	If there was some internal company	9	not materially change my opinion and
10	documents, you know, stating that there	10	conclusions about the case.
11	was potentially higher exposures, I'm not	11	You know, I think I have you
12	privy to those documents. I haven't	12	know, there's very clear reasons in my
13	reviewed those.	13	opinion why, NDMA, even if he had
14	BY MR. VAUGHN:	14	hypothetically been exposed to higher
15	Q. Okay. Earlier in your answer, you	15	doses, could not have been the cause of
16	said, "I understand Mr. Roberts' alleged	16	his hepatocellular carcinoma.
17	exposure to some NDMA-contaminated Valsartan	17	So I don't think it is necessarily
18	pills."	18	relevant to the scope of of my role as,
19	What do you mean by "alleged	19	again, not a toxicologist. I'm
20	exposure"?	20	commenting commenting on the
21	A. The exposures that are you know,	21	plausibility that NDMA-contaminated
22	there's I say alleged because there's	22	Valsartan could have been plausibly been
23	uncertainty in the actual dose exposure of NDMA	23	the factor that caused Mr. Roberts to
24	in a particular pill.	24	develop HCC.
25	You know, I think we acknowledge	25	My opinion does not actually
	Page 351		Page 353
1	that we don't know specifically what the dose	1	change depending on even if he was exposed
2	was that he was exposed to, nor do we	2	to a higher dose. There are very clear
3	necessarily know, you know, to what extent he's	3	reasons why it could not have been the
4	adherent with medications. There are variables	4	NDMA.
5	that impact our assessment of what his actual	5	I'm happy to articulate that in
6	dose exposure was.	6	more detail if you'd like, but it's in my
7	I don't deny that he filled	7	expert report, of course. But even if I
8	prescriptions for Valsartan that were	8	had that data, it would not change my
9	NDMA-contaminated based on, you know, the batch	9	<mark>opinio</mark> n.
10	lots and things like this. But I don't I	10	BY MR. VAUGHN:
11	can't there ' a lot of uncertainty in terms	11	Q. So regardless of how much NDMA
12	of what is his actual cumulative dose exposure.	12	Mr. Roberts was exposed to, it wouldn't change
13	Q. And ZHP's counsel didn't provide	13	your opinion?
14	you with any calculations that ZHP did on what	14	MS. ROSE: Object to the form.
15	those does levels would have been in those	15	Misstates the witness testimony.
16	pills?	16	THE WITNESS: Yeah. What I'm
17	MS. ROSE: Object to the form.	17	relying on is, you know, my opinion is he
18	THE WITNESS: Yeah. You know, the	18	likely already had hepatocellular
19	answer's the same. I don't have any	19	carcinoma when he was first exposed to
20	internal, you know, company documents	20	NDMA. I I provide some very clear
21	related to, you know, what they what	21	evidence of this in my expert report. You
22	they thought the NDMA levels were in their	22	know, there's multiple ways of looking at
23	pills. Only what	23	this.
24	BY MR. VAUGHN:	24	But among them are just looking at
25	Q. If those	25	very simple tumor volume doubling times.
1			

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1	You know, we talked about the stage of	1	BY MR. VAUGHN:
2	cancer that he was diagnosed with. It's	2	Q. Understood. And I was planning to
3	really important to highlight that when he	3	get to it if we had time in the deposition.
4	was diagnosed in, you know, April you	4	What's the fastest growth rate for
5	know, July/April of 2018, he did not have	5	HCC?
6	early stage hepatocellular carcinoma. He	6	A. Yeah. So, you know, we look at
7	had multiple lesions. There were two	7	this mostly in terms of tumor volume doubling
8	lesions that were clear clearly	8	time. I'm pulling up my report to give you
9	LI-RADS 5 lesions that were, you know,	9	very precise numbers.
10	HCC, the largest of which, from my	10	Okay. So tumor volume doubling
11	recollection, was 5.8 centimeters in	11	time, again, these are these estimates are
12	diameter.	12	aggregated. It's actually coming from a
13	You don't get a 5.8-centimeter		meta-analysis of many different studies to get
14	diameter HCC overnight. That does not	14	as accurate of representation of the range of
15	occur quickly. That takes a long time to	15	growth rates as possible.
16	get there, to that size. And fortunately,	16	The most so if you take the
17	this is something that's been studied in	17	95-percent kind of confidence interval in terms
18	great detail across many studies. There's	18	of one extreme to the other, the most sort of
19	a lot of interest in understanding growth	19	aggressive growth rates are on the scale of
20	rates of HCC so we can understand what to	20	3.9 months for tumor volume doubling time.
21	expect in patients and how to	21	And so I have table where I kind of
22	prognosticate.	22	go through these calculations. The average is
23	And in my expert report, you know,	23	about 4.6 months for tumor volume doubling
24	I cite the literature, and I give the	24	times, and the slower one are 5.3 months of
25	different ranges, the average tumor volume	25	tumor volume doubling time.
	Page 355		D 257
	1 480 000		Page 357
1	doubling time, the extreme cases of very	1	Q. So 3.9 months is the quickest
1 2	doubling time, the extreme cases of very aggressive growth and and very slow	2	Q. So 3.9 months is the quickest doubling time of HCC?
	doubling time, the extreme cases of very		Q. So 3.9 months is the quickest doubling time of HCC?A. Tumor volume doubling time, yes.
2	doubling time, the extreme cases of very aggressive growth and and very slow growth. And I ran simulations for all of those.	2 3 4	 Q. So 3.9 months is the quickest doubling time of HCC? A. Tumor volume doubling time, yes. Q. Is it your opinion that NDMA cannot
2 3	doubling time, the extreme cases of very aggressive growth and and very slow growth. And I ran simulations for all of those. And no matter what assumption you	2 3 4 5	 Q. So 3.9 months is the quickest doubling time of HCC? A. Tumor volume doubling time, yes. Q. Is it your opinion that NDMA cannot cause cirrhosis?
2 3 4 5 6	doubling time, the extreme cases of very aggressive growth and and very slow growth. And I ran simulations for all of those. And no matter what assumption you take, even if I assumed the most	2 3 4 5 6	Q. So 3.9 months is the quickest doubling time of HCC? A. Tumor volume doubling time, yes. Q. Is it your opinion that NDMA cannot cause cirrhosis? A. So I think, you know, in in
2 3 4 5 6 7	doubling time, the extreme cases of very aggressive growth and and very slow growth. And I ran simulations for all of those. And no matter what assumption you take, even if I assumed the most aggressive form of hepatocellular	2 3 4 5 6 7	Q. So 3.9 months is the quickest doubling time of HCC? A. Tumor volume doubling time, yes. Q. Is it your opinion that NDMA cannot cause cirrhosis? A. So I think, you know, in in animal literature, you know, at a sufficiently
2 3 4 5 6 7 8	doubling time, the extreme cases of very aggressive growth and and very slow growth. And I ran simulations for all of those. And no matter what assumption you take, even if I assumed the most aggressive form of hepatocellular carcinoma with the fastest growth rates	2 3 4 5 6 7 8	Q. So 3.9 months is the quickest doubling time of HCC? A. Tumor volume doubling time, yes. Q. Is it your opinion that NDMA cannot cause cirrhosis? A. So I think, you know, in in animal literature, you know, at a sufficiently high dose, you know, I do think that NDMA can
2 3 4 5 6 7 8 9	doubling time, the extreme cases of very aggressive growth and and very slow growth. And I ran simulations for all of those. And no matter what assumption you take, even if I assumed the most aggressive form of hepatocellular carcinoma with the fastest growth rates that are observed in in you know, in	2 3 4 5 6 7 8 9	Q. So 3.9 months is the quickest doubling time of HCC? A. Tumor volume doubling time, yes. Q. Is it your opinion that NDMA cannot cause cirrhosis? A. So I think, you know, in in animal literature, you know, at a sufficiently high dose, you know, I do think that NDMA can likely cause hepatic fibrosis and likely
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	D 070		P. 000
1	Page 358 made the claim that NDMA could have caused the	1	Page 360 I I think I may have scrolled through again
$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	cirrhosis. So I so I did look into this	2	sometime in the past, probably, ten days.
3	specifically. Obviously, I first started in	3	Q. Did you see it before you came to
4	the context of NDMA-contaminated Valsartan to	4	your expert opinions in this case, before you
5	try to be as specific to the case as possible,	5	submitted a report?
6	and then, you know, when I didn't really find	6	A. Yes, I i believe I reviewed
7	any scientifically compelling evidence that	7	this, you know, as well as other kind of, you
8	NDMA-contaminated Valsartan could plausibly	8	know, kind of regular, you know, documents from
9	cause cirrhosis, I I broadened my search to	9	other large institutions like the WHO, IARC. I
10	look at different nitrosamine-related studies.	10	reviewed a lot of that initially in the context
11	Q. And on page 20 of your expert	11	of writing my expert report, but I did take
12	report, you said there's no scientific evidence	12	another passthrough of elements of this
13	to substantiate that NDMA is a cause of	13	probably, like I said, in the last ten days or
14	cirrhosis, correct?	14	so.
15	A. All right. Page 28, you said?	15	Q. And did you see any evidence in
16	Q. Page 20. Here. I can screen share	16	here that NDMA would cause cirrhosis?
17	to help you?	17	A. You'd have to point me to specific
18	A. I'm just trying to find the exact	18	areas to refresh my memory. It's hard to keep
19	quote.	19	track of what was in which document, but
20	Q. There we go. Right here: "No	20	Q. No problem. Let me see.
21	scientific evidence to substantiate NDMA causes	21	A. Yeah. I appreciate that.
22	cirrhosis."	22	Q. All right. So it's PDF page 41
23	A. Yes. And it the context here	23	is where I'm at, where it's talking about
1	I'm referring to she's talking about in the	24	hepatic.
25	context of Mr. Roberts' HCC. So implicit here	25	And "hepatic" means liver, correct?
	Page 359		Page 361
1	is that I'm talking about the context for a	1	A. Yes.
2	human patient.	2	Q. Okay.
3	Q. Okay.	3	A. I'm sorry. You said 41, you
		١.,	110 01 71 10 707
4	A. Yeah.	4	said? Oh, I'm sorry. 40 PDF page 41.
5	MR. VAUGHN: Kathryn, can we do	5	Q. That's where I'm at now. Sorry.
5 6	MR. VAUGHN: Kathryn, can we do 2023 United States Health and Human	5 6	Q. That's where I'm at now. Sorry. That's where it starts on hepatic. That's
5 6 7	MR. VAUGHN: Kathryn, can we do 2023 United States Health and Human Services. This is going to be Exhibit 17.	5 6 7	Q. That's where I'm at now. Sorry. That's where it starts on hepatic. That's where it starts talking about this study called
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1	Page 362	1	Page 364
1	A. Uh-huh. Yes, I see that.	1	just don't think it's strong enough, correct?
2	Q. These are humans that it's talking	2	MS. ROSE: Object to the form. THE WITNESS: I believe what I
3	about, right?	3	
4	A. Yes. I do remember reviewing	4	state is there's no scientific evidence to
5	these. Thank you for showing me because I I	5	substantiate the claim. So what I'm
6	recall these. Again, these are case reports	6	referring there is there's no there's
7	from a long time ago. You know, from the '70s	7	no there's no there's no evidence in
8	and the '80s. I think I may have reviewed more	8	the literature of sufficient quality to
9	than these.	9	make a causal claim in humans between NDMA
10	And I recall another case report	10	and cirrhosis. I'm not
11	where someone had a toxic exposure to NDMA and	11	BY MR. VAUGHN:
12	likely other things, and on the autopsy there	12	Q. And you agree sorry.
13	was cirrhosis. I remember seeing a report	13	A. That's good.
14	along those lines as well.	14	Q. And you agree that you can't give
15	So yeah. I acknowledge that those	15	it to humans intentionally to study it,
16	are humans that have been reported, but the	16	correct?
17	issue again, you know, with case reports and	17	A. Yes, I would agree with that.
18	case studies is that there's no ability to	18	Q. And so would there ever be enough
19	assess associations or magnitude of risk	19	evidence for you for this association if you
20	factors. There's no accounting of potential	20	can't actually study it in humans?
21	biases or or limitations.	21	MS. ROSE: Object to the form.
22	It's it's purely reporting	22	THE WITNESS: So it is possible, I
23	through the lens of of the provider or	23	think, to do a very high quality study
24	whoever's running the case report, a series of	24	using, you know, high quality causal
25	events. They say that someone had NDMA	25	inference methodology that, if
	Page 363		Page 365
1	exposure. Later they were found to have	1	demonstrated consistently across multiple
2	cirrhosis on autopsy or, you know, or they	2	studies, that that I think could make a
3	became ill. They were found to have jaundice.	3	sufficient could meet a sufficient
4	We know nothing about whether	4	standard of evidence to make that claim.
5	that's attributable to NDMA. We know nothing	5	My opinion, though, is that we don't have
6	about, you know, whether or not they had	6	such literature in humans to make that
7	preexisting cirrhosis or if they had	7	claim.
	significant alcohol use that led to cirrhosis,	8	But but yes. It would not
	if they were taking other substances in	9	require a randomized trial. I mean, I
10	addition to being exposed to NDMA.	10	acknowledge that it would not be ethical
11	So you have to be very, very	11	to do a randomized control trial in
12	cautious in trying to translate something from	12	humans. So we are reliant on
13	a case report. And this is a theme I keep	13	observational studies, but you have to
14	highlighting. But this is not compelling	14	look at quality of individual
15	scientific evidence to establish causality in	15	observational studies and measure those
16	my view as a clinician scientist and a	16	very carefully when you're making this
17	clinician between NDMA exposure and and	17	adjudication of is a causal inference
18	cirrhosis.	18	warranted both generally and, of course,
19	So that that's my view about	19	as applied specifically in this case to
20	these case reports. But yes, I've reviewed	20	Mr. Roberts is what my my primary
21	these. I've seen these case reports as well as	21	concern is.
22	others.	22	BY MR. VAUGHN:
23	Q. In your expert report, you said	23	Q. And do you see on the next page
24	there's no scientific evidence.	24	where, then, United States Health and Human
25	There's scientific evidence. You	25	Services talks about two men who got liver

Page 366 Page 368 1 cirrhosis after just using NDMA in a research 1 like, from the 1950s. I don't know what 2 laboratory? 2 type of research laboratory they worked 3 A. Yes. I think that's probably what 4 I was referring to when I was talking about the 4 Like I said, I'm not a basic 5 case where on autopsy, you know, the case 5 scientist, so I have no idea what the reports where there was an NDMA exposure, and 6 specific context of this research lab was. 7 then on autopsy there was cirrhosis. 7 So I don't know. I don't know what the 8 8 But like I said, we don't know if plausible range was in that, and they 9 9 that cirrhosis was already present. Those -don't seem to specify it here. 10 those individuals could have already had 10 And I think the other case study 11 cirrhosis from a multitude of different causes. you mentioned on the page that said an 11 unknown quantity of NDMA. So it may not 12 They happened to take NDMA in very, very high 12 13 doses or potentially other exposures in 13 even be known. 14 addition to NDMA. And -- you know, and then it 14 But again, these are extremely old 15 might be an incidental finding on the autopsy 15 case reports, and you have to be very skeptical of particular very old case 16 that there is cirrhosis. 16 17 There's no ability to directly 17 reports where the quality of the data and 18 attribute causally that the NDMA in a case the reporting or what could have been a 18 19 report was the reason that these individuals 19 adjudicated or identified was more -- more 20 had cirrhosis. It's just not possible to make 20 limited back then. 21 that claim. 21 So it's really, really difficult to 22 O. Okay. That's the same thing you're 22 really find -- find anything that's really concrete and useful from, you know, a 1954 23 saying for Mr. Roberts is he already had 23 24 cirrhosis, so it couldn't have been NDMA that 24 case study. 25 caused it, right? 25 Page 367 Page 369 1 MS. ROSE: Object to the form. 1 BY MR. VAUGHN: 2 THE WITNESS: Well, I'm saying 2 Q. Do you know why people research 3 multiple things. I'm saying from the 3 NDMA in the laboratory setting? scientific literature, I don't even know MS. ROSE: Object to the form. 4 4 5 if it's -- there's not in any evidence in 5 THE WITNESS: Yeah. I mean, in the 6 the scientific literature to -- to 6 laboratory setting, you know, as I've 7 7 demonstrate that it's -- it's -- it's -already -- I mentioned and I understand, 8 8 it's causally linked at all in humans, and I concede that in animals, you know, 9 certainly at that relevant dose exposure, 9 it -- it's demonstrated that NDMA in very 10 10 to cause cirrhosis in humans. So that high doses can cause hepatic fibrosis, can cause different types of liver cancer, not 11 evidence standard is not met. 11 12 But certainly in the specific case 12 just HCC, but bile duct cancers as well. 13 of Mr. Roberts, as you know, it's very 13 And so it's studied in that context 14 clear that he already has cirrhosis at the 14 for itself carcinogenicity in animals and 15 time he's first exposed. So obviously, 15 to help justify -- or I suppose it helps 16 the NDMA could not have been the cause. I 16 to justify human studies to explore that potential relationship more as potential 17 mean, the cirrhosis was antecedent to his 17 effects in humans. 18 first NDMA exposure. 18 19 BY MR. VAUGHN: 19 BY MR. VAUGHN: 20 Q. How much NDMA do you think someone Q. And do you see here where they say, 20 21 just in the lab doing research would actually "The patient showed improved liver function 21 22 be exposed to? 22 after three months with no exposure to NDMA"? 23 MS. ROSE: Object to the form. 23 A. Sorry. Yeah. So I mean, this is THE WITNESS: There's no way for me 24 another thing that makes me a little bit 24

25 skeptical of this case report from 1954 where

to -- to know. I don't know. This is,

25

Page 370 1 they say that cirrhosis was discovered during 2 operate, and and there was improvement in 3 liver function. 4 I don't know what they mean by 5 "liver function." I'm not sure what labs 6 they're referring to or on what basis they're 7 saying that liver function was improved. 8 As I said before, you know, 9 cirrhosis is generally considered to be binary. 10 You know, if cirrhosis is there if cirrhosis 11 is there and you manage the patient as such. 12 So without kind of revisiting that 13 study in more detail to see on what basis 14 they're saying that, I don't necessarily know 15 what they're referring to; but I'm skeptical 16 for those reasons. 17 Because certainly once there's 18 cirrhosis present, there's already a state of 19 liver injury that is ir you know, generally 20 irreversible. So so I'm not sure what 21 they're referring to there. 22 Q. Do you see here where the United 23 States Health and Human Services says, 24 "Hepatotoxicity is the most prominent 25 characteristic systemic effect of NDMA Page 371 1 resulting in' what is this? 2 Central lobular necrosis? 3 Did I say that right? Page 372 Page 373 1 really are questioning, but it's very much 2 related to this, that I have to emphasize that all of these animal studies study animals that have normal livers at baseline. They're exposing normal healthy, you know, rodents or whatever animal model they're using. They have a healthy liver. They're given high-dose NDMA, 8 and they observe what happens. 9 It's important it's important to recognize that that is not analogous to 10 recognize that that is not analogous to 11 Mr. Roberts' case. He already has cirrhosis. 12 Why is that relevant? 13 If you look at Sawyer's expert 14 report, he talks about the mechanism of 15 carcinogenesis attributable to NDMA. 16 NDMA needs to be activated in the 17 liver. It needs to be metabolically activated by enzymes in the liver to toxic metabolites. 19 The NDMA itself is not the issue. It's the toxic metabolites. 21 That's important exp
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2 Central lobular necrosis? 2 relevant because we actually change the way we
prostrict terrain medications in we time
4 A. Yeah. Central lobular necrosis. 4 cirrhosis is present. If cirrhosis is present,
5 Q "and hemorrhage, fibrosis, 5 it will not reliably metabolize things.
6 cirrhosis, and ascites." 6 So there is a highly plausible
7 Do you disagree with the United 7 reason to expect that even if, hypothetically,
8 States Health and Human Services on that? 8 you know, I were to grant that there is, you
9 A. So let me take a look. 9 know, some concern that NDMA could cause liver
This is page 42, right? 10 cancer in humans, which, again, I don't grant
11 Q. Uh-huh. 11 based on the scientific literature we talked
12 A. Yeah. So this again, you know, the 12 about, there's no reason to believe that that
13 preceding sentence is saying this is animal 13 would apply to somebody who already has
14 species. So in several animal so again, 14 cirrhosis who's unable to reliably metabolize
15 this is from the animal literature. 15 NDMA to the toxic metabolites. There's
And no, I don't disagree with that 16 literally no data in such a patient, animal or
17 from the animal literature. As I've stated, I 17 human, where they've studied NDMA exposures
18 recognize that high-dose NDMA, you do see these 18 specifically in a baseline cohort of animals or
19 changes in rodents of liver injury, liver 19 humans who already have cirrhosis. So
20 fibrosis, and the attendant complications, 20 Q. So it's your keep going.
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20 fibrosis, and the attendant complications, 21 including HCC. 20 Q. So it's your keep going. 21 A. That's fine. That's good.
20 fibrosis, and the attendant complications, 20 Q. So it's your keep going. 21 including HCC. 21 A. That's fine. That's good. 22 You know, but my my broader 22 Q. So is it your opinion that

1	Page 374 THE WITNESS: What I'm saying is	1	Page 376 these as, you know, the best available
		2	model for what could potentially happen in
2	that even the animal literature doesn't	3	a human; but that doesn't absolve
3	apply to him. I mean, it's it's		· · · · · · · · · · · · · · · · · · ·
4	it's another cautionary tale of why you	4	researchers and scientists and clinicians
5	can't blindly translate animals studies to	5	from doing the requisite research and work
6	humans. There are other independent	6	in humans specifically to see if that
7	reasons for that.	7	translation is warranted.
8	But specifically bringing it back	8	BY MR. VAUGHN:
9	to the case of Mr. Roberts, he has	9	Q. In the Health and Human Services
10	cirrhosis at the time he's exposed to	10	there has been a great deal of research
11	NDMA; and there's literally no relevant	11	performed to investigate the molecular
12	literature that I'm aware of, animal or	12	mechanisms and pathophysiology of NDMA-related
13	otherwise, where they look at NDMA	13	hepatic effects. George, et al. 2019 published
14	exposure in the setting of organisms that	14	a succinct review of this research.
15	already have cirrhosis.	15	Did you review George, et al. 2019
16	So we don't know really anything at	16	in coming to your opinions in this case?
17	all about what to expect in those	17	A. I mean, I reviewed a variety of
18	patients.	18	literature related, you know, from the this
19	BY MR. VAUGHN:	19	is again from the animal literature.
20	Q. And for the mechanisms of	20	Q. Uh-huh.
21	hepatoxicity of NDMA, the United States Health	21	A. So so yes. I reviewed a variety
22	and Human Services discusses how NDMA was given	22	of different studies that that discuss
23	to both dogs and rats and has been used as a	23	the the the mechanisms of hepatoxicity
24	model for human liver fibrosis and its sequelae	24	and carcinogenesis of NDMA and animal studies.
25	of cirrhosis, portal hypertension, and	25	I don't I can't immediately
	Page 375		Page 377
1	hepatocellular carcinoma for nearly 40 years.	1	recall if George, et al. is one of them, but
2	And so do you you disagree that	2	I'm certain I reviewed, if not that one, then
3	dogs and rats can be used as a model for human	3	closely related ones that talks about this.
4	fibrosis with NDMA?	4	Q. Okay. Because Dr. Siddiqui listed
5	MS. ROSE: Object to the form.	5	that as one of her materials considered when
6	THE WITNESS: So no, I don't	6	she was
7	disagree that animal models are used in	7	A. Okay.
8	in this fashion, you know, all the time.	8	Q saying that NDMA could cause
9	The part that I'm trying to clarify	9	cirrhosis in humans. And you said she had no
10	and demonstrate my disagreement is that	10	scientific support for that.
11	you cannot blindly translate findings from	11	Do you retract that statement?
12	animal research to humans. You need	12	MS. ROSE: Object to the form and
13	dedicated humans studies, which often take	13	colloquy.
14	time and long-term follow-up to	14	THE WITNESS: No, I don't retract
15	demonstrate that the same things are	15	that statement. Again, my statement is
16	observed in humans.	16	that there's no there's no, you know,
17	I mean, this is a very, you know,	17	substantiated literature in humans to
18	well-known phenomena called the	18	demonstrate that NDMA is causally linked
19	translation translational gap. You're	19	to cirrhosis, you know, in studies that
20	not guaranteed to see the same things in	20	are scientifically and methodologically
21	animal studies as human studies. I mean,	21	sound with sufficient effect sizes and
22	there there are very famous prominent	22	power, et cetera, to to demonstrate
23	examples that serve as cautionary tales	23	that conclusively.
24	for doing just that.	24	So I stand by that statement. And
25	So yes. In the lab, sure, we use	25	I think, you know, if you want to talk
, , ,	bo yes. In the lab, suite, we use	L 4J	i annik, you know, n you want to talk

	Page 378		Page 380
1	about George, et al., I think you'd have	1	A. Yes.
2	to show it to me again just to jog my	2	Q. Okay. And is formaldehyde a potent
3	memory.	3	hepatotoxin?
4	BY MR. VAUGHN:	4	A. Formaldehyde I believe in, you
5	Q. Okay. So it's not necessarily that	5	know, sufficient concentrations can be yeah,
6	there's not any evidence at all out there.	6	it can be a toxin. Yeah, absolutely.
7	It's just not good enough evidence for you,	7	Q. And at what and at what
8	correct?	8	concentration of formaldehyde would you need?
9	MS. ROSE: Object to the form.	9	A. I couldn't give you a number off
10	THE WITNESS: Yeah. I think I've	10	the top of my head.
11	articulated that a couple of times that,	11	Q. Okay. And do you see here where
12	you know, the human literature that is	12	it's talking about initiating events leading to
13	that is purporting to associate NDMA with	13	hepatic fibrosis in NDMA-exposed organisms?
14	something like cirrhosis, they're based on	14	What what's an "organism"?
15	case studies that are from, you know, 80	15	A. An organism is a living it's a,
16	years ago, 70 years ago, where you cannot	16	you know, an animal is an organism. A human is
17	systemically study NDMA as a risk factor	17	an organism. It's a living it's a living
18	because they're not analytical studies.	18	entity, I suppose.
19	So no. That is that is not a valid way	19	Q. Okay. So United States Health and
20	to determine a risk factor.	20	Human Services thinks that NDMA and its
21	Really no clinician who understands	21	degradant such as formaldehyde can end up
22	what a risk factor is would rely on that	22	leading to hepatic fibrosis in NDMA-exposed
23	as evidence to say that NDMA causes this.	23	humans, right?
24	You need much more high quality evidence	24	MS. ROSE: Object to the form.
25	to demonstrate that.	25	THE WITNESS: So, you know, they're
	Page 379		Page 381
1	BY MR. VAUGHN:	1	not specifying which organisms here.
2	Q. So you just think there's	2	They're not being very specific. So I
3	insufficient evidence of NDMA causing cirrhosis	3	mean, this may have been from primarily
4	in humans?	4	animal literature. I'm not certain. They
5	MS. ROSE: Object to the form.	5	would have to be more specific and
6	Asked and answered.	6	probably cite specific references to
7	THE WITNESS: I mean, I can restate	7	clarify what they're saying.
8	the same thing I said. I mean, to my	8	BY MR. VAUGHN:
9	standard, which I think is a commonly held	9	Q. Okay.
10	standard for, I think, reputable	10	A. Organisms is an extremely broad
11	clinicians and clinician scientists, you	11	term.
12	want to see high quality medical	12	Q. All right. Can you name me one
13	literature that is an analytic study,	13	study in which NDMA has been studied in an
14	right. So not descriptive analytic.	14	animal and was not carcinogenic, one animal,
15	These are high quality observational	15	one organism?
16	studies, for instance, or interventional	16	MS. ROSE: Object to the form.
17	studies, which I agree we can't do in this	17	THE WITNESS: I mean, off the top
1 4 0	setting, to demonstrate using causal	18	of my head, I you know, I don't think
18			all the animal studies with NDMA exposures
19	inference methodology that there is a	19	-
19 20	inference methodology that there is a strong and consistent effect that's	20	look at that specifically as an end point.
19 20 21	inference methodology that there is a strong and consistent effect that's observed between NDMA and cirrhosis. And	20 21	look at that specifically as an end point. I mean, there are are I think quite a
19 20 21 22	inference methodology that there is a strong and consistent effect that's observed between NDMA and cirrhosis. And we don't have that.	20 21 22	look at that specifically as an end point. I mean, there are are I think quite a few animal studies where they're looking
19 20 21 22 23	inference methodology that there is a strong and consistent effect that's observed between NDMA and cirrhosis. And we don't have that. BY MR. VAUGHN:	20 21 22 23	look at that specifically as an end point. I mean, there are are I think quite a few animal studies where they're looking at other types of cancers, for instance.
19 20 21 22	inference methodology that there is a strong and consistent effect that's observed between NDMA and cirrhosis. And we don't have that.	20 21 22	look at that specifically as an end point. I mean, there are are I think quite a few animal studies where they're looking

	Page 382		Page 384
1	intending to study specifically liver	1	repeated injury and repair induced by these
2	effects, I you know, I can't name off		metabolites may also be involved in the
3	the top of my head any specific study, you	3	mechanism of liver cancer from NDMA exposure."
4	know, to my recollection that did not	4	Did I read that correctly?
5	identify, you know you know, some	5	A. You read that with one word I
6	association with hepatic fibrosis or liver	6	think you might have misstated intermediates.
7	cancer with, you know, high-dose NDMA	7	I think you said intermediaries.
8	exposure.	8	Q. Thank you.
9	BY MR. VAUGHN:	9	A. That's okay. But aside from that
10	Q. And so is it your opinion that	10	word word, yes, you read correctly.
11	humans are the only organisms that aren't going	11	But when I read this, this I
12	to have hepatic fibrosis as a result of NDMA	12	
13	exposure?	13	what I've been saying kind of throughout the
14	MS. ROSE: Object to the form.	14	
15	THE WITNESS: No. That's not my	15	So one thing that's immediately
16	opinion. I mean, this this has been	16	clear immediately clear from this statement
17	studied in, you know, selected types of	17	is the DNA damage induced to animal studies is
18	organisms; but it's not studied to this	18	from the reactive intermediates of DNA
19	degree, you know, with sufficient evidence	19	metabolism.
20	at the dosing ranges in particular that	20	Farther up the page, you know, if
21	are used in animal studies. There's no	21	you scroll through, it talks about how the
22	demonstration that, you know, that we	22	liver and the, you know, the esthetic P chrome
23	would necessarily see the same thing in	23	50 system is the mechanism by which NDMA gets
24	humans.	24	processed and metabolized into these toxic
25	So I'm not I'm not saying that	25	intermediates, including formaldehyde and, you
	Page 383		Page 385
1	it's not possible that in the future a	1	know, methyldiazonium and others.
2	well-conducted study could could	2	So that's that's an important
3	demonstrate some potential link between	3	point, which is why I highlighted that it takes
	NDMA and some adverse, you know, related	4	a healthy liver to do that. And if you have
4	· · · · · · · · · · · · · · · · · · ·	-	
5	event. That's possible. It's possible to	5	cirrhosis, your liver is not healthy. You do
5 6	event. That's possible. It's possible to do a very high quality study.	5 6	cirrhosis, your liver is not healthy. You do not have normal metabolic activity. We don't
5 6 7	event. That's possible. It's possible to do a very high quality study. What I'm saying is there's no	5 6 7	cirrhosis, your liver is not healthy. You do not have normal metabolic activity. We don't even know if a if a cirrhotic liver could
5 6 7 8	event. That's possible. It's possible to do a very high quality study. What I'm saying is there's no evidence currently in humans that	5 6	cirrhosis, your liver is not healthy. You do not have normal metabolic activity. We don't even know if a if a cirrhotic liver could actually metabolize NDMA to those reactive
5 6 7 8 9	event. That's possible. It's possible to do a very high quality study. What I'm saying is there's no evidence currently in humans that demonstrates this. So we, therefore,	5 6 7 8 9	cirrhosis, your liver is not healthy. You do not have normal metabolic activity. We don't even know if a if a cirrhotic liver could actually metabolize NDMA to those reactive intermediaries. So that's one important point.
5 6 7 8 9 10	event. That's possible. It's possible to do a very high quality study. What I'm saying is there's no evidence currently in humans that demonstrates this. So we, therefore, can't make the conclusion for Mr. Roberts	5 6 7 8 9 10	cirrhosis, your liver is not healthy. You do not have normal metabolic activity. We don't even know if a if a cirrhotic liver could actually metabolize NDMA to those reactive intermediaries. So that's one important point. The second point from this sentence
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25 also asked and answered. 25 you know, if this is the mechanism that's	16 17 18 19 20 21 22 23	cancer, in my view that is not a sufficient latency period for a cancer to develop, for carcinoma to development. That's my that's my position. Q. And based on what you were saying earlier, it's your opinion that someone with liver disease is at a decreased risk from NDMA exposure?	17 18 19 20 21 22 23	When a patient with autoimmune hepatitis has progressed already to cirrhosis, we don't use predni Prednisone anymore. We use prednisolone because we can't rely on the liver metabolize to prednisolone, which is the active intermediate.
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	D 400		D 000
1	Page 390 hypothesized in demonstrated animals, if	1	Page 392 now, Nina.
2	· ·	2	THE VIDEOGRAPHER: Off the record
$\frac{2}{3}$	we try to translate this to humans and we assume that the same things would apply in	3	at 5:14.
4	humans, you wouldn't need a functioning	4	
5	liver to metabolize NDMA to a toxic	5	(Whereupon, a break was taken.) THE VIDEOGRAPHER: We are back on
6	intermediate.	6	the record at 5:27.
7	So so yes, it's very plausible	7	BY MR. VAUGHN:
8	that a patient would cirrhosis would	8	Q. All right. Doctor, I want to go
9	actually be relatively protected from, you	9	back to your expert report, which is Exhibit 1,
10	know, NDMA-related toxicity if, in fact,	10	and I'm going to be on page 33 to start with.
11	that were to exit.	11	A. Sure.
12	BY MR. VAUGHN:	12	Q. For your tumor doubling time that
13	Q. You say it's very plausible.	13	you were talking about earlier, you cite to, I
14	Do you have any scientific evidence	14	believe, it's Nathani Number 95. Let's see
15	specific to NDMA on that opinion?	15	here.
16	A. I don't because, as I as I've	16	95 is Nathani, correct?
17	stated numerous times, there's really	17	A. Yes.
18	limited there's no data in patients with	18	Q. Okay. And when you were doing this
19	cirrhosis in humans being exposed to NDMA or in	19	calculation can you explain this calculation
20	animals with preexisting cirrhosis.	20	real quick to me, what you're doing, how it
21	Q. Okay. Let's go to page 94 of this.	21	works for tumor volume doubling time?
22	Do you see here, "Other factors	22	A. Sure. So I'm using a method that's
23	influencing susceptibility"?	23	are commonly used in these studies where they
24	Read the sentence out loud to the	24	study tumor volume doubling time.
25	jury from the United States Health and Human	25	But basically, you start with the
	Page 391		Page 393
1	Services.	1	assumption that a tumor is roughly spherical.
2	A. Sorry. I'm scrolling to 94.	2	So the first thing I'm presenting there is the
3	Q. I have it highlighted if that's	3	formula for the volume of a sphere. So V is
4	easier for you.	4	is volume. That's equal to one-sixth times pie
5	A. Okay. Sure.	5	times D cubed where D is the diameter. So
6	MS. ROSE: The doctor should if	6	that's the first part.
7	you'd like to look at the document, you	7	The second part I'm just
8	can look at the document.	8	rearranging and solving for D, which, again, is
9	THE WITNESS: Yeah. I just want to	9	diameter. Because oftentimes, you know, we
10	get a sense of the context really quickly	10	don't typically report the volume of a tumor on
11	to understand what the what they're	11	a radiology report. We measure things in terms
12	talking about here.	12	of diameter.
13	BY MR. VAUGHN:	13	So that's why, you know, for
14	Q. It's under the bolded heading	14	instance, on Mr. Roberts' imaging reports they
15	"Other Factors Influencing Susceptibility."	15	say, you know, the tumor 5.8 centimeters in
16	A. Sure. I see it.	16	diameter.
17	Q. All right. Can you read the	17	So that's why I'm trying to solve
18	highlighted sentence from the Health and Human	18	this to put everything in terms of diameter to
19	Services?	19	make it more translatable to what you would see
20	A. Sure. So it says, "Other factors	20	on imaging.
21	influencing susceptibility. Because the liver	21	Q. Why is it that you have to assume
22	is the primary target of NDMA toxicity,	22	the spherical shape?
23	individuals with liver disease may be at	23 24	A. Yeah. You have to make certain
24 25	increased risk factors from NDMA exposure." MR. VAUGHN: We can take a break	25	assumptions. Obviously, it's possible for that tumor's not going to be a perfect sphere.
43	IVIN. VACCITIV. WE CALL LAKE A DIEAK	43	mai tumoi s not going to be a perfect sphere.

Page 394 Page 396 1 It might be, you know, a little bit lobulated 1 commonly used in these studies to help us 2 and -- but you have to make assumptions -- for 2 understand and approximate tumor volume 3 the purposes of just doing the studies, you doubling time. 4 make the assumption. 4 And so you're assuming that They typically are roughly 5 Mr. Roberts' liver cancer was also spherical, 5 6 spherical. If you look at tumors, they tend 6 correct? to -- just the way they grow, they grow in all 7 MS. ROSE: Object to the form. dimensions, and they tend to grow roughly in an 8 THE WITNESS: For the purpose of spherical shape. But, you know, I acknowledge 9 these calculations, you know, I'm assuming 10 that that's an approximation that we use. 10 that, you know, if Mr. Roberts' had a 11 And, you know, we make 11 5.8-centimeter diameter tumor, for the 12 approximations like this in a lot of areas in 12 purpose of calculations, I'm assuming it's 13 medicine to help us understand biological and 13 roughly spherical. 14 pathophysiologic processes. 14 I'm not saying that in actuality, 15 So but I like I said, this is a --15 it was a perfect sphere. But, you know, 16 this is a fairly standard assumption that's to approximate doubling time, we -- we 16 17 used in this type of literature for, you know, 17 make an assumption that's sphere. You tumor volume doubling time. 18 know, the formula you have to try to put 18 19 Q. And so you're making the assumption 19 together to -- to accurately get the 20 that it was spherical when it started the 20 topography of an HCC mathematically would 21 cancer, and then it remained spherical 21 be, you know, extraordinarily complex; and 22 throughout it's progression, correct? 22 it's -- for that reason, it's not 23 MS. ROSE: Object to the form. 23 typically done that way. THE WITNESS: Yeah. I'm -- I'm --24 24 So yes. It's an assumption I make, 25 25 but I think it's a very reasonable yeah. Right. Page 395 Page 397 1 So I'm basically -- to do these 1 assumption. It's a very common assumption 2 calculations, to simplify the calculations 2 used in the medical literature. and make things easily translatable, I'm 3 3 BY MR. VAUGHN: making the assumption that the tumors are 4 Q. And you note here "aggressive 4 5 roughly spherical, yes. 5 growth being 3.9 months," correct? 6 BY MR. VAUGHN: A. 6 Q. And did you review the imaging in 7 7 Q. And where -- where did you get this 2018 of Mr. Roberts' cancer? 8 definition that aggressive growth is a doubling 9 Yes, I did. time -- or doubling every 3.9 months? So in this study that we talked 10 Q. And was his cancer spherical? 10 I -- I would have to look at it about, Reference Number 95, they -- it's a 11 11 12 again in detail. It's sometimes very tough to 12 meta-analysis of many different studies. I 13 assess because we -- you, oftentimes, may need 13 can't remember the specific number. It might 14 a good three-dimensional reconstruction of an 14 have been roughly 20 studies, I think. Oh, 15 image, a CT scan or an MRI. 15 yeah, it's 20 studies. I state it right there. 16 You know, we look at it in terms of 16 Sorry. 17 slices, typically, you know, in a coronal or a 17 Yeah. On page 33 I state that it's 18 sagittal or a transverse axis. And, you know, 18 a meta-analysis of 20 different studies, that 19 we -- I was not presented with any of the all were trying to estimate tumor volume 20 three-dimensional reconstructions. So it's -doubling time. And what this study did was, it 20

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100 (Pages 394 - 397)

21 looked at the distribution of growth rates in

23 were reported in those studies; and they created -- pulled estimates to arrive at a

25 distribution. And that allowed them to

22 tumor volume doubling times that were -- that

24

23 spherical.

24

21 it's tough for me to be able to say confidently

25 but like I said, this is an assumption that is

I doubt it's perfectly spherical;

22 is it -- is it spherical or is it not

PageID: 114049

Case 1:19-md-02875-RMB-SAK

101 (Pages 398 - 401)

He had identifiable lesions that

acknowledged that there's a margin of error in

were macroscopically visible. And sure I

what the exact size is going to be, and that

22

23

24

imaging done?

25 the dates again.

23

24

22 approximately April of 2016 when he had this

A. Sorry. I'm just trying to think of

	Page 402		Page 404
1	may be related to the fact that it's not a	1	
2	perfect sphere, as you have already stated.	2	percent from the 95-percent confidence
3	But he had an identifiable lesion.	3	interval.
4	And, you know, from Dr. Chernyak's expert	4	So, you know, whatever adjective
5	report, she classified it as a LI these are	5	you use to describe it, I mean, that's what I'm
6	LI-RADS 3 lesions. These have intermediate	6	referring to. So I'm giving you the very
7	probabilities at that time of of being HCC.	7	precise definition of what that is. It is
8	And many of these LI-RADS 3 lesions over time	8	the
9	will, in fact, declare themselves to be	9	Q. I appreciate that.
10	LI-RADS 5 lesions and cancer.	10	A. Sure, sure.
11	Q. And do you believe that these were	11	MR. VAUGHN: Kathryn, can you drop
12	LI-RADS 3 lesions, or were you just relying	12	in 2021 Nathani HCC tumor volume doubling
13	Dr. Chernyak?	13	time.
14	A. I'm relying a lot on Dr. Chernyak's	14	MS. AVILA: Yes, and it's
15	assessment here. Again, I'm familiar with the	15	Exhibit 18.
16	LI-RADS criteria, and I do look for them	16	MR. VAUGHN: Thank you for that.
17	myself, you know; but, you know, like I said,	17	(Whereupon, Exhibit 18, Author
18	I'm not a I'm not a diagnostic radiologist.	18	manuscript entitled, "Hepatocellular
19	And in particular for the smaller	19	Carcinoma Tumor Volume Doubling Time: A
20	lesions where some of the findings are more	20	Systemic Review and Meta-analysis," by
21	subtle, I'm more reliant on a diagnostic	21	Piyush Nathan, et al., was marked for
22	radiologist with relevant expertise to make	22	identification.)
23	this determination.	23	BY MR. VAUGHN:
24	For me, it's I'm able to more	24	Q. All right. Doctor, and this is the
25	confidently identify things like LI-RADS 5	25	study that you cited, right, by Nathani to
	Page 403		Page 405
1	lesions where some of the features are a little	1	2021?
2	bit more obvious to to my eye, you know, who	2	A. Yes.
3	doesn't, you know, look at, you know, MRI	3	Q. Do you see here where the author
1	images every single day all day.		- · · · · · · · · · · · · · · · · · · ·
1 4		4	defines rapid as a tumor double volume time of
4 5		5	defines rapid as a tumor double volume time of less than three months?
5	So for these particular lesions,		less than three months?
5 6	So for these particular lesions, I'm I'm more differential to Dr. Chernyak,	5	less than three months? A. Sure.
5 6 7	So for these particular lesions, I'm I'm more differential to Dr. Chernyak, but Dr. Chernyak has the relevant expertise.	5 6 7	less than three months? A. Sure. Q. Okay. And that's not the timeframe
5 6	So for these particular lesions, I'm I'm more differential to Dr. Chernyak, but Dr. Chernyak has the relevant expertise. You know, she works in a liver transplant	5 6	less than three months? A. Sure. Q. Okay. And that's not the timeframe that you applied, right?
5 6 7 8 9	So for these particular lesions, I'm I'm more differential to Dr. Chernyak, but Dr. Chernyak has the relevant expertise. You know, she works in a liver transplant center. She's an abdominal diagnostic	5 6 7 8	less than three months? A. Sure. Q. Okay. And that's not the timeframe that you applied, right? You applied 3.9 months, correct?
5 6 7 8 9 10	So for these particular lesions, I'm I'm more differential to Dr. Chernyak, but Dr. Chernyak has the relevant expertise. You know, she works in a liver transplant center. She's an abdominal diagnostic radiologist.	5 6 7 8 9 10	less than three months? A. Sure. Q. Okay. And that's not the timeframe that you applied, right? You applied 3.9 months, correct? A. Right. So what I'm what I'm
5 6 7 8 9 10 11	So for these particular lesions, I'm I'm more differential to Dr. Chernyak, but Dr. Chernyak has the relevant expertise. You know, she works in a liver transplant center. She's an abdominal diagnostic radiologist. And so yes. If she classifies it	5 6 7 8 9 10 11	less than three months? A. Sure. Q. Okay. And that's not the timeframe that you applied, right? You applied 3.9 months, correct? A. Right. So what I'm what I'm doing is I'm taking the results of their
5 6 7 8 9 10 11 12	So for these particular lesions, I'm I'm more differential to Dr. Chernyak, but Dr. Chernyak has the relevant expertise. You know, she works in a liver transplant center. She's an abdominal diagnostic radiologist. And so yes. If she classifies it as LI-RADS 3 and has the appropriate	5 6 7 8 9 10 11 12	less than three months? A. Sure. Q. Okay. And that's not the timeframe that you applied, right? You applied 3.9 months, correct? A. Right. So what I'm what I'm doing is I'm taking the results of their studies.
5 6 7 8 9 10 11 12 13	So for these particular lesions, I'm I'm more differential to Dr. Chernyak, but Dr. Chernyak has the relevant expertise. You know, she works in a liver transplant center. She's an abdominal diagnostic radiologist. And so yes. If she classifies it as LI-RADS 3 and has the appropriate justification, I have no reason to doubt that.	5 6 7 8 9 10 11	less than three months? A. Sure. Q. Okay. And that's not the timeframe that you applied, right? You applied 3.9 months, correct? A. Right. So what I'm what I'm doing is I'm taking the results of their studies. You're highlighting something from
5 6 7 8 9 10 11 12 13 14	So for these particular lesions, I'm I'm more differential to Dr. Chernyak, but Dr. Chernyak has the relevant expertise. You know, she works in a liver transplant center. She's an abdominal diagnostic radiologist. And so yes. If she classifies it as LI-RADS 3 and has the appropriate justification, I have no reason to doubt that. Q. Is aggressive growth synonymous to	5 6 7 8 9 10 11 12 13 14	less than three months? A. Sure. Q. Okay. And that's not the timeframe that you applied, right? You applied 3.9 months, correct? A. Right. So what I'm what I'm doing is I'm taking the results of their studies. You're highlighting something from the methods.
5 6 7 8 9 10 11 12 13 14 15	So for these particular lesions, I'm I'm more differential to Dr. Chernyak, but Dr. Chernyak has the relevant expertise. You know, she works in a liver transplant center. She's an abdominal diagnostic radiologist. And so yes. If she classifies it as LI-RADS 3 and has the appropriate justification, I have no reason to doubt that. Q. Is aggressive growth synonymous to rapid growth to you?	5 6 7 8 9 10 11 12 13	less than three months? A. Sure. Q. Okay. And that's not the timeframe that you applied, right? You applied 3.9 months, correct? A. Right. So what I'm what I'm doing is I'm taking the results of their studies. You're highlighting something from the methods. Q. Uh-huh.
5 6 7 8 9 10 11 12 13 14 15 16	So for these particular lesions, I'm I'm more differential to Dr. Chernyak, but Dr. Chernyak has the relevant expertise. You know, she works in a liver transplant center. She's an abdominal diagnostic radiologist. And so yes. If she classifies it as LI-RADS 3 and has the appropriate justification, I have no reason to doubt that. Q. Is aggressive growth synonymous to rapid growth to you? A. Yeah. So so my use of the word	5 6 7 8 9 10 11 12 13 14 15	less than three months? A. Sure. Q. Okay. And that's not the timeframe that you applied, right? You applied 3.9 months, correct? A. Right. So what I'm what I'm doing is I'm taking the results of their studies. You're highlighting something from the methods. Q. Uh-huh. A. If you look at the results of what
5 6 7 8 9 10 11 12 13 14 15 16	So for these particular lesions, I'm I'm more differential to Dr. Chernyak, but Dr. Chernyak has the relevant expertise. You know, she works in a liver transplant center. She's an abdominal diagnostic radiologist. And so yes. If she classifies it as LI-RADS 3 and has the appropriate justification, I have no reason to doubt that. Q. Is aggressive growth synonymous to rapid growth to you? A. Yeah. So so my use of the word "aggressive" here, I'm I'm really just	5 6 7 8 9 10 11 12 13 14 15 16 17	less than three months? A. Sure. Q. Okay. And that's not the timeframe that you applied, right? You applied 3.9 months, correct? A. Right. So what I'm what I'm doing is I'm taking the results of their studies. You're highlighting something from the methods. Q. Uh-huh. A. If you look at the results of what they actually found in terms of tumor volume
5 6 7 8 9 10 11 12 13 14 15 16 17 18	So for these particular lesions, I'm I'm more differential to Dr. Chernyak, but Dr. Chernyak has the relevant expertise. You know, she works in a liver transplant center. She's an abdominal diagnostic radiologist. And so yes. If she classifies it as LI-RADS 3 and has the appropriate justification, I have no reason to doubt that. Q. Is aggressive growth synonymous to rapid growth to you? A. Yeah. So so my use of the word "aggressive" here, I'm I'm really just trying to I'm not trying to imply anything	5 6 7 8 9 10 11 12 13 14 15 16 17 18	less than three months? A. Sure. Q. Okay. And that's not the timeframe that you applied, right? You applied 3.9 months, correct? A. Right. So what I'm what I'm doing is I'm taking the results of their studies. You're highlighting something from the methods. Q. Uh-huh. A. If you look at the results of what they actually found in terms of tumor volume doubling times in the results section, you'll
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	So for these particular lesions, I'm I'm more differential to Dr. Chernyak, but Dr. Chernyak has the relevant expertise. You know, she works in a liver transplant center. She's an abdominal diagnostic radiologist. And so yes. If she classifies it as LI-RADS 3 and has the appropriate justification, I have no reason to doubt that. Q. Is aggressive growth synonymous to rapid growth to you? A. Yeah. So so my use of the word "aggressive" here, I'm I'm really just trying to I'm not trying to imply anything beyond the fact that it's more it's the	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	less than three months? A. Sure. Q. Okay. And that's not the timeframe that you applied, right? You applied 3.9 months, correct? A. Right. So what I'm what I'm doing is I'm taking the results of their studies. You're highlighting something from the methods. Q. Uh-huh. A. If you look at the results of what they actually found in terms of tumor volume doubling times in the results section, you'll see that 4.6 months is the pooled average
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	So for these particular lesions, I'm I'm more differential to Dr. Chernyak, but Dr. Chernyak has the relevant expertise. You know, she works in a liver transplant center. She's an abdominal diagnostic radiologist. And so yes. If she classifies it as LI-RADS 3 and has the appropriate justification, I have no reason to doubt that. Q. Is aggressive growth synonymous to rapid growth to you? A. Yeah. So so my use of the word "aggressive" here, I'm I'm really just trying to I'm not trying to imply anything beyond the fact that it's more it's the fastest growth rate that I'm studying here	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	less than three months? A. Sure. Q. Okay. And that's not the timeframe that you applied, right? You applied 3.9 months, correct? A. Right. So what I'm what I'm doing is I'm taking the results of their studies. You're highlighting something from the methods. Q. Uh-huh. A. If you look at the results of what they actually found in terms of tumor volume doubling times in the results section, you'll see that 4.6 months is the pooled average doubling time, with a 95-percent confidence
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	So for these particular lesions, I'm I'm more differential to Dr. Chernyak, but Dr. Chernyak has the relevant expertise. You know, she works in a liver transplant center. She's an abdominal diagnostic radiologist. And so yes. If she classifies it as LI-RADS 3 and has the appropriate justification, I have no reason to doubt that. Q. Is aggressive growth synonymous to rapid growth to you? A. Yeah. So so my use of the word "aggressive" here, I'm I'm really just trying to I'm not trying to imply anything beyond the fact that it's more it's the fastest growth rate that I'm studying here informed by that by the literature that I've	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	less than three months? A. Sure. Q. Okay. And that's not the timeframe that you applied, right? You applied 3.9 months, correct? A. Right. So what I'm what I'm doing is I'm taking the results of their studies. You're highlighting something from the methods. Q. Uh-huh. A. If you look at the results of what they actually found in terms of tumor volume doubling times in the results section, you'll see that 4.6 months is the pooled average doubling time, with a 95-percent confidence interval of 3.9 to 5.3.
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	So for these particular lesions, I'm I'm more differential to Dr. Chernyak, but Dr. Chernyak has the relevant expertise. You know, she works in a liver transplant center. She's an abdominal diagnostic radiologist. And so yes. If she classifies it as LI-RADS 3 and has the appropriate justification, I have no reason to doubt that. Q. Is aggressive growth synonymous to rapid growth to you? A. Yeah. So so my use of the word "aggressive" here, I'm I'm really just trying to I'm not trying to imply anything beyond the fact that it's more it's the fastest growth rate that I'm studying here informed by that by the literature that I've cited.	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	less than three months? A. Sure. Q. Okay. And that's not the timeframe that you applied, right? You applied 3.9 months, correct? A. Right. So what I'm what I'm doing is I'm taking the results of their studies. You're highlighting something from the methods. Q. Uh-huh. A. If you look at the results of what they actually found in terms of tumor volume doubling times in the results section, you'll see that 4.6 months is the pooled average doubling time, with a 95-percent confidence interval of 3.9 to 5.3. So that's the data that I'm using.
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	So for these particular lesions, I'm I'm more differential to Dr. Chernyak, but Dr. Chernyak has the relevant expertise. You know, she works in a liver transplant center. She's an abdominal diagnostic radiologist. And so yes. If she classifies it as LI-RADS 3 and has the appropriate justification, I have no reason to doubt that. Q. Is aggressive growth synonymous to rapid growth to you? A. Yeah. So so my use of the word "aggressive" here, I'm I'm really just trying to I'm not trying to imply anything beyond the fact that it's more it's the fastest growth rate that I'm studying here informed by that by the literature that I've cited. You know, I I'm not sure what	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	less than three months? A. Sure. Q. Okay. And that's not the timeframe that you applied, right? You applied 3.9 months, correct? A. Right. So what I'm what I'm doing is I'm taking the results of their studies. You're highlighting something from the methods. Q. Uh-huh. A. If you look at the results of what they actually found in terms of tumor volume doubling times in the results section, you'll see that 4.6 months is the pooled average doubling time, with a 95-percent confidence interval of 3.9 to 5.3. So that's the data that I'm using. Q. Okay. And then on page 2, it does
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	So for these particular lesions, I'm I'm more differential to Dr. Chernyak, but Dr. Chernyak has the relevant expertise. You know, she works in a liver transplant center. She's an abdominal diagnostic radiologist. And so yes. If she classifies it as LI-RADS 3 and has the appropriate justification, I have no reason to doubt that. Q. Is aggressive growth synonymous to rapid growth to you? A. Yeah. So so my use of the word "aggressive" here, I'm I'm really just trying to I'm not trying to imply anything beyond the fact that it's more it's the fastest growth rate that I'm studying here informed by that by the literature that I've cited.	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	less than three months? A. Sure. Q. Okay. And that's not the timeframe that you applied, right? You applied 3.9 months, correct? A. Right. So what I'm what I'm doing is I'm taking the results of their studies. You're highlighting something from the methods. Q. Uh-huh. A. If you look at the results of what they actually found in terms of tumor volume doubling times in the results section, you'll see that 4.6 months is the pooled average doubling time, with a 95-percent confidence interval of 3.9 to 5.3. So that's the data that I'm using.

102 (Pages 402 - 405)

1	Page 406 Mr. Roberts was not Asian and did	1	Page 408
	not have Hep B, correct?	2	Q. Okay. And 5.3 times 7, is that 37.1?
$\begin{vmatrix} 2 \\ 3 \end{vmatrix}$	A. That's true. He did not have	3	A. Yes.
4	Hep B, and he was not Asian.	4	Q. Okay. And so if the tumor volume
5	Q. Okay. Let me go to page 6 of this	5	doubling time was 2.2, would the accurate way
6	study.	6	to do that be to times it by 7?
7	Do you see down here earlier I	7	A. Yeah. That appears correct based
8	asked you what the quickest time was for tumor	8	on what you're showing me, yes, yes.
9	volume doubling for HCC, and you testified	9	Q. Which would be 15 which would
10	3.9 months.	10	15.4 months?
11	Based on this study, do you see	11	A. Sure, 15.4 months.
12	here where it's actually the quickest they note	12	Q. So
13	is 2.2 months for doubling?	13	A. But again sorry. Go ahead. Go
14	A. Yeah. So I think I acknowledged	14	ahead.
15	that it's possible for things to be faster. I	15	Q. So if he had the most aggressive
16	did say that it's possible that, you know,	16	form of cancer from that study, it would have
17	there can be doubling times that are beyond the	17	started 15 months before his diagnosis,
18	95-percent confidence interval bands. I	18	correct?
19	acknowledge that.	19	MS. ROSE: Object to the form.
20	But you look at the the range in	20	THE WITNESS: That's not exactly
21	the distribution of data to identify plausible	21	correct. You'd actually have to extend
22	scenarios. So yeah. I I acknowledge that	22	let's see.
23	it's possible for doubling time to be faster,	23	The issue is I think you may need
24	sure.	24	to add more rows of data below this
25	Q. And did you model out what it would	25	because there would be additional tumor
	Page 407		Page 409
1	look like if it was doubling every 2.2 months	1	diameters and additional rows on this
2	in Mr. Roberts?	2	table. They'd have to to model out to
3	A. No, I didn't model that particular	3	see what the diameter would have been at
4	case. I modeled, again, based on the extremes	4	that time.
5	from the distribution.	5	BY MR. VAUGHN:
6	Q. And if it was 2.2 months, is the	6	Q. And does the tumor doubling keep
7	right way to do that, then, to be timesing	7	going all the way to zero to the inception of
8	[sic] 2.2 by 7 to figure out how many months	8	the cancer, or does it stop being a valid
9	earlier he would be at based on your	9	formula at 1 centimeter?
10	calculations?	10	A. That's a great question. I you
11	MS. ROSE: Object to the form.	11	know, I am not immediately sure, you know, to
12	THE WITNESS: That does not sound	12	what what I'll say is things are very tough
13	immediately accurate to me. I think you	13	to macroscopically visualize on imaging when
14	have to really apply this through the	14	they're extremely small.
15	formulas that I laid out.	15	You know, when they're, you know,
16	BY MR. VAUGHN:	16	on the range of certainly less than
17	Q. Can you see the expert can you	17	.1 centimeters. Things are very tough to
18	see am I back on the expert report screen	18	discern when they're extremely, extremely
19	sharing?	19	small.
20	A. Yes.	20	So I presume that that could not be
21	Q. Okay. Is 3.9 times 7, 27.3?	21	modeled accurately in these studies because you
22	I can screen share a calculator if	22	have to be able to measure it on imaging.
	I need me to.	23	Q. What is the
	i ficcu file to.	L 4.)	O. What is the
23			
1	A. Sure. So it's 3.9 times 7. Yes, that's 27.3.	24 25	A. I think Q. Sorry.

103 (Pages 406 - 409)

	P. 410		D 410
1	Page 410 A. That's okay. Go ahead.	1	Page 412 to again, there's multiple risk factors, but
2	Q. What does the word "indolent" mean?	2	I think the primary one is his MASH-related
3	A. Sorry. Where are you looking?	3	cirrhosis. Yeah.
4	Q. I'm not looking at the study.	4	So I mean, but but I think we
5	Are you familiar with the word	5	were highlighting his he's more likely to
6	"indolent"?	6	have a slow-growing tumor. So so there's
7	A. Indolent. Yes.	7	less reason to assume that he would have
8	Q. Indolent. Sorry.	8	extremely rapid growth.
9	What does that mean?	9	He's more likely to be on the side
10	A. Yeah. Indolent generally means,	10	of the distribution of a slow-growing tumor,
11	you know, very slow growing or not you know,	11	which, again, is modeled in that table I showed
	it's something on that spectrum. Not really	12	you. So if we took, you know, the assumption
13	not actively showing significant growth or very	13	of slow growth, which is 5.3 months, then we
14	slow growing. That's usually how indolent is	14	absolutely would have expected that he you
15	used.	15	know, he would have had, you know, lesions in
16	Q. Can you see here in the study side	16	the liver at that time.
17	where they talk about rapidly growing tumors	17	So I think that's, once again,
18	among studies conducted in Asia sorry, in	18	consistent with what I'm what I'm modeling
19	recent studies with diverse liver disease	19	here.
20	etiologies reported more indolent growth among	20	Q. And so if we go with the slow
21	patients with nonviral liver disease.	21	growth, which would be what you would expect
22	What is "nonviral liver disease"?	$\begin{vmatrix} 21\\22\end{vmatrix}$	with HCC from someone with NASH, when the
23	A. Nonviral means not related to	23	radiology report from 4/18/16 was done, he
24	Hepatitis B or Hepatitis C.	24	should have nearly a 2-centimeter tumor at that
25	Q. And so HCCs that are not related to	25	time, right?
		-	time, right.
	D 411	1	D 412
1	Page 411 Hen A or sorry. Scratch that.	1	Page 413 MS. ROSE: Object to the form.
$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	Hep A or sorry. Scratch that.	1 2	MS. ROSE: Object to the form.
2	Hep A or sorry. Scratch that. HCCs that are not related to Hep B	2	MS. ROSE: Object to the form. THE WITNESS: So look, these are
2 3	Hep A or sorry. Scratch that. HCCs that are not related to Hep B or Hep C typically grow slower, correct?	2 3	MS. ROSE: Object to the form. THE WITNESS: So look, these are not guaranteed guarantees. There's
2 3 4	Hep A or sorry. Scratch that. HCCs that are not related to Hep B or Hep C typically grow slower, correct? A. Yes. I'd say so.	2 3 4	MS. ROSE: Object to the form. THE WITNESS: So look, these are not guaranteed guarantees. There's variation within every etiology of liver
2 3 4 5	Hep A or sorry. Scratch that. HCCs that are not related to Hep B or Hep C typically grow slower, correct? A. Yes. I'd say so. Q. And the study authors say that's	2 3 4 5	MS. ROSE: Object to the form. THE WITNESS: So look, these are not guaranteed guarantees. There's variation within every etiology of liver disease. It's not like every single
2 3 4 5 6	Hep A or sorry. Scratch that. HCCs that are not related to Hep B or Hep C typically grow slower, correct? A. Yes. I'd say so. Q. And the study authors say that's particularly important in the western world.	2 3 4 5 6	MS. ROSE: Object to the form. THE WITNESS: So look, these are not guaranteed guarantees. There's variation within every etiology of liver disease. It's not like every single patient with NASH-related cirrhosis will
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 1
       slowly, he's almost guaranteed to have
 2
       already had hepatocellular carcinoma when
 3
       he was -- when he was first exposed to
 4
       NDMA-contaminated Valsartan.
 5
           MR. VAUGHN: I pass the witness.
 6
           MS. ROSE: Can we take a break just
 7
       for a second?
 8
           THE VIDEOGRAPHER: Off the record,
 9
       5:49.
10
           (Whereupon, a break was taken.)
           THE VIDEOGRAPHER: We are back on
11
12
       the record at 6:06.
13
           MS. ROSE: Dr. Mahmud, I want to
14
       thank you so much for taking time out of
15
       your schedule for this deposition today.
16
           I don't have any questions for you
17
       at this time, so I think the deposition is
18
       concluded.
19
           THE WITNESS: Okay.
20
           THE VIDEOGRAPHER: That concludes
21
       today's deposition. The time is 6:07.
22
           (The witness is excused.)
23
           (Deposition of Nadim Mahmud, M.D.,
24
       concluded at 6:07 p.m. EDT.)
25
                                               Page 415
 1
            CERTIFICATE
2
3
          I, SUZANNE J. STOTZ, a Certified
5 Court Reporter, Registered Professional
6 Reporter, Certified Realtime Reporter, and
7 Notary Public in and for the State of New
8 Jersey, do hereby certify that the foregoing is
9 a true and accurate transcript of the
10 stenographic above-captioned matter.
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